No. 15-17510

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, et al.,
Plaintiffs-Appellants,

v.

MARGARET A. HAMBURG,
in her official capacity as Commissioner,
United States Food and Drug Administration, et al.,
Defendants-Appellees

and

ELANCO ANIMAL HEALTH,
Intervenor-Defendant-Appellee.

On Appeal from the United States District Court,
Northern District of California,
Nos. 14-cv-04932-YGR & 14-cv-04933-YGR (consolidated)
Honorable Yvonne Gonzales Rogers

ANSWERING BRIEF OF FEDERAL APPELLEES

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GLOSSARY

BLM	Bureau of Land Management
EA	Environmental assessment
EIS	Environmental impact statement
ER	Excerpts of record
FONSI	Finding of no significant impact
NEPA	National Environmental Policy Act
SER	Supplemental excerpts of record

INTRODUCTION

Under the exhaustion of administrative remedies doctrine, a party cannot seek "judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *McKart v. United States*, 395 U.S. 185, 193 (1969) (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51 (1938)).

Federal regulations require a party to file a citizen petition requesting that the Food and Drug Administration (FDA) take a specific action before that party seeks to compel agency action in court. Neither the Center for Food Safety nor any of its co-plaintiffs filed a citizen petition with the FDA challenging the agency's review of environmental impacts for eighteen applications for new animal drugs under the National Environmental Policy Act (NEPA). Nor did any of the plaintiffs file a citizen petition asking the FDA to consider new circumstances and information that could implicate the agency's approval of any of the new animal drug applications. Because plaintiffs did not file a citizen petition with the FDA, they *never* presented their NEPA arguments to the agency.

Plaintiffs instead filed suit in federal court under the Administrative Procedure Act (APA), seeking declaratory and injunctive relief. Plaintiffs asked the district court to vacate the approval of the new animal drugs and to ban the use of ractopamine (an animal feed additive) pending a new NEPA review. The district court refused to

grant plaintiffs this sweeping relief without allowing the FDA to consider plaintiffs' claims in the first instance. Because plaintiffs must file a citizen petition with the FDA before seeking judicial review, the district court dismissed their complaints. This appeal followed.

JURISDICTIONAL STATEMENT

On November 6, 2014, the Center for Food Safety, the Center for Biological Diversity, and the Sierra Club filed a complaint under the APA alleging that the FDA violated NEPA when it approved certain applications for new animal drugs. *See* Excerpts of Record (ER) 197–222. On the same day, the Humane Society of the United States, the United States Farm Workers of America, and the Animal Legal Defense Fund filed a complaint raising similar allegations. ER 165–96. The district court had subject-matter jurisdiction under 28 U.S.C. § 1331.

On March 5, 2015, the district court consolidated the cases. ER 236 (Dkt. No. 32). On April 1, 2015, the district court granted Elanco Animal Health's motion to intervene. ER 237 (Dkt. No. 45). Elanco then moved to dismiss the complaints for plaintiffs' failure to exhaust their administrative remedies, and, on November 5, 2015, the district court granted Elanco's motion. ER 1–16.

On November 19, 2015, the district court entered final judgment dismissing plaintiffs' complaints. ER 21. Plaintiffs timely filed their notice of appeal on December 18, 2015. ER 17–20. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

(1) Whether the district court erred when it dismissed plaintiffs' complaints for failure to exhaust administrative remedies because plaintiffs failed to file a citizen petition with the FDA before seeking judicial review of their claims.

(2) Assuming the district court had discretion to waive the citizen petition requirement, whether the district court clearly abused its discretion when it did not waive the exhaustion requirement.

STATEMENT OF THE CASE

I. Legal background

A. FDA's approval of new animal drugs

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act to regulate drug manufacturing, marketing, and distribution. 21 U.S.C. § 301, et seq. "The Act's most substantial innovation was its provision for premarket approval of new drugs," *Wyeth v. Levine*, 555 U.S. 555, 566 (2009), including new animal drugs, 21 U.S.C. § 360b.

The federal government has a "substantial interest in ensuring the safety and effectiveness of animal drugs." *United States v. Argent Chem. Labs., Inc.*, 93 F.3d 572, 576 (9th Cir. 1996). Before a drug manufacturer can market a new animal drug (or a new combination of existing animal drugs), it must apply for FDA approval. *See* 21 U.S.C. § 360b(b)(1); *see also id.* § 321(v) (defining "new animal drug"). The FDA will approve a new animal drug only if, after an extensive

application and approval process, it determines that the drug is "safe and effective for use." *Id.* § 360b(b)(1).

This test is meant "to be a rigorous one." *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 630 (1973). "Obtaining approval takes a long time and costs a lot of money, for the FDA requires thorough experimentation to determine both the drug's effects on animals and whether its residues persist in the animals and enter the food chain." *United States v. 9/1 Kg. Containers*, 854 F.2d 173, 174 (7th Cir. 1988).

Before it approves a new animal drug application, the FDA analyzes, among other things, the drug's effect on human food safety as well as animal health. *See* 21 U.S.C. § 360b(c); 21 C.F.R. § 514.1. Once it has completed these reviews and concluded that approval is warranted, the FDA publishes a notice of its decision. *See, e.g.*, New Animal Drugs for Use in Animal Feeds; Ractopamine; Tylosin, 74 Fed. Reg. 66,914 (Dec. 17, 2009) (approving the use of a two-way combination of swine feeds formulated with ractopamine hydrochloride and tylosin phosphate).

The Trade Secret Act, 18 U.S.C. § 1905, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), prohibit the FDA from disclosing information from a new animal drug application before the FDA has approved the drug. 21 C.F.R. § 25.50(b); *see also Pharm. Mfrs. Ass'n v. Weinberger*, 411 F. Supp. 576, 578 (D.D.C. 1976) ("The FDA is

well versed in the areas of company trade secrets and confidential information."). Confidentiality is important because it protects the drug manufacturer's valuable information. *See* 2 Food and Drug Admin. § 22:1 (2016) (discussing the protection of confidential business information); Gerrit M. Beckhaus, A New Prescription to Balance Secrecy and Disclosure in Drug-Approval Processes, 46 U. Mich. J.L. Reform 135, 149–51 (2012) (same).

After it has approved a new animal drug, the FDA can withdraw or suspend its approval of the drug if circumstances change. *See* 21 U.S.C. § 360b(e). The FDA could find, based on "experience or scientific data," that the animal drug is no longer safe. *Id.* § 360b(e)(1)(A). The FDA can also rely on "new evidence" that was not contained in the application to conclude that the new animal drug is no longer shown to be safe. *Id.* § 360b(e)(1)(B). Or the FDA might find that "new information," together with evidence submitted with the application, demonstrates a lack of substantial evidence of effectiveness to support the drug's approval. *Id.* § 360b(e)(1)(C).

The FDA, for example, took actions to withdraw the approval of enrofloxacin, an animal drug used to control poultry mortality associated with Escherichia coli (E. coli). *See* Withdrawal of Enrofloxacin for Poultry, http://go.usa.gov/xjwYA (last updated Dec. 2, 2014). After it reexamined the safety profile of enrofloxacin, the FDA concluded that it presented a health hazard to humans. *See*

Enrofloxacin for Poultry; Opportunity for Hearing, 65 Fed. Reg. 64,954, 64,954–55 (Oct. 31, 2000). The FDA subsequently withdrew its approval of the drug. *See* Enrofloxacin Withdrawal of Approval, 70 Fed. Reg. 44,048 (Aug. 1, 2005).

B. National Environmental Policy Act

Congress enacted NEPA, 42 U.S.C. § 4321, et seq., "to reduce or eliminate environmental damage and to promote 'the understanding of the ecological systems and natural resources important to' the United States." *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 756 (2004) (quoting 42 U.S.C. § 4321). NEPA is an "essentially procedural" statute, meant to ensure that federal agencies reach "a fully informed and well-considered decision." *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 558 (1978).

The "twin aims" of NEPA require an agency "to consider every significant aspect of the environmental impact of a proposed action" and then "inform the public that it has indeed considered environmental concerns in its decisionmaking process." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 97 (1983) (internal quotation marks omitted). NEPA's requirements are not absolute; they "are to be implemented consistent with other programs and requirements." *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 449 F.3d 1016, 1034 (9th Cir. 2006).

An agency can satisfy NEPA even if it is unable to meet the public disclosure requirements. *See, e.g.*, *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 635 F.3d 1109, 1116 (9th Cir. 2011) (*Mothers for Peace II*). That is because NEPA compels the agency to comply with its requirements "to the fullest extent possible." *Weinberger v. Catholic Action of Hawaii/Peace Educ. Project*, 454 U.S. 139, 142 (1981) (quoting 42 U.S.C. § 4332(C)). NEPA's decision-making and public disclosure goals are "compatible," but they are "not necessarily coextensive." *Id.*

NEPA does not contain any substantive environmental standards or mandate any particular results. *Barnes v. Dep't of Transp.*, 655 F.3d 1124, 1131 (9th Cir. 2011). NEPA instead requires an agency to take a "hard look" at the potential consequences of a proposed federal action. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989); *see also* 42 U.S.C. § 4332(C). An agency can satisfy this requirement without public participation. *See Weinberger*, 454 U.S. at 143; *Mothers for Peace II*, 635 F.3d at 1116.

The FDA complies with "NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act." 21 C.F.R. § 25.1. The NEPA review process begins when the FDA receives from an applicant or petitioner an environmental assessment or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners

on the NEPA-related aspects of their requested actions. *See id.* §§ 25.10(c), 25.15. The FDA safeguards data and information submitted with an application for a new animal drug, as well as any information disclosed during the FDA's review of the application. *See id.* §§ 514.11, 514.12. That includes data and information from NEPA-related analyses. *Id.* § 25.50(a).

When it amended its NEPA regulations in 1997, the FDA addressed concerns regarding public participation in the review process. *See* Revision of Policies and Procedures, 62 Fed. Reg. 40,570, 40,589–90 (July 29, 1997). NEPA requires the FDA to comply with its statutory requirements "to the fullest extent possible," *id.* 40,589 (quoting 42 U.S.C. § 4332), which means that the FDA must comply with NEPA requirements "unless existing law applicable to [its] operations expressly prohibits or makes compliance impossible," *id.* (quoting 40 C.F.R. § 1500.6). To that end, "[i]f FDA is not prohibited under the [Trade Secret Act] and the [Federal Food, Drug, and Cosmetic Act] from disclosing specific environmental information before FDA takes action, FDA will disclose that environmental information at the earliest possible time before action is taken." *Id.*

FDA cannot, however, disclose environmental information before approving an application unless the applicant has already made the information public or has given the FDA permission to do so. *See* 21 C.F.R. § 25.50(b). To the extent that the Trade Secret Act, the Federal

Food, Drug, and Cosmetic Act, or other applicable laws make it impossible for the FDA to disclose environmental information before an approval, the FDA will disclose that information after the approval and to the extent permitted by such laws.

When it enacted NEPA, Congress established the Council of Environmental Quality and gave it authority to issue regulations to help federal agencies determine what actions are subject to NEPA's requirements. *Pub. Citizen*, 541 U.S. at 757 (citing 40 C.F.R. § 1500.3).

EIS. For "major Federal actions significantly affecting the quality of the human environment," 42 U.S.C. § 4332(C), a federal agency must prepare an environmental impact statement (EIS) to evaluate the consequences of the proposed action, *see* 40 C.F.R. §§ 1502.12–1502.14. The content of an EIS is dictated in part by "the underlying purpose and need to which the agency is responding." 40 C.F.R. § 1502.13. The agency must analyze alternatives that are consistent with the nature and scope of that action. *See City of Carmel-by-the-Sea v. Dep't of Transp.*, 123 F.3d 1142, 1155 (9th Cir. 1997).

EA. If the federal action will not "significantly affect[ ] the quality of the human environment," 42 U.S.C. § 4332(C), an agency may prepare an environmental assessment (EA), 40 C.F.R. §§ 1501.3(b), 1501.4, 1508.9; *see also Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503–04 (D.C. Cir. 2010) (describing the difference between an EIS and an EA). An EA is a "concise public

document . . . that serves to . . . [b]riefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement [EIS] or a finding of no significant impact [(FONSI)]." 40 C.F.R. § 1508.9(a)(1).

Categorical exclusion. Under regulations promulgated by the Council on Environmental Quality, agencies may categorically exclude certain types of actions from the requirement of preparing an EIS or an EA, so long as the actions do not "individually or cumulatively have a significant effect on the human environment." 40 C.F.R. § 1508.4.

"Categorical exclusions are not exemptions or waivers of NEPA review; they are simply one type of NEPA review." Memorandum from the Council on Envtl. Quality to Heads of Fed. Departments & Agencies 2 (Nov. 23, 2010).[1] Agencies establish categorical exemptions "on the basis of past experience" with proposed activities. *Id.* "Once established, categorical exclusions provide an efficient tool to complete the NEPA environmental review process for proposals that normally do not require more resource-intensive EAs or EISs." *Id.*

In a typical new animal drug approval, if a categorical exclusion does not apply, then an EA is prepared to evaluate whether the approval will significantly affect the quality of the human environment.

[1] Available at https://ceq.doe.gov/current_developments/new_ceq_nepa_guidance.html (last visited Aug. 11, 2016).

If the approval is found to significantly affect the quality of the human environment, then an EIS is prepared.

Relevant here, the FDA relied on a categorical exclusion for certain new animal drugs and therefore did not need to prepare an EA or an EIS for these actions. *See* 21 C.F.R. § 25.33. The FDA does not ordinarily prepare an EA or an EIS for a new animal drug application that is based on "[a] combination of previously approved animal drugs" and does not increase the use of the drugs. *Id.* § 25.33(a)(2); *see also* ER 61.

C. Exhaustion of administrative remedies

1. Exhaustion under the APA

NEPA does not provide a private right of action for a plaintiff to enforce its provisions against an agency. *Earth Island Inst. v. Forest Serv.*, 697 F.3d 1010, 1013 (9th Cir. 2012). A plaintiff must therefore seek review under the APA of agency actions that allegedly violate NEPA. *Id.*; *see also* 5 U.S.C. § 702.

Section 702 of the APA states that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.SC. § 702. This provision establishes judicial review of agency actions. *See Darby v. Cisneros*, 509 U.S. 137, 146 (1993).

Section 704 explains when judicial review is available. *See id.* In relevant part, Section 704 states: "Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section . . . unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority." 5 U.SC. § 704.

Interpreting Section 704, the Supreme Court explained that judicial review is available when: (1) "an aggrieved party has exhausted all administrative remedies expressly prescribed by statute or agency rule," *Darby*, 509 U.S. at 146; or (2) "an agency rule requires appeal before review and the administrative action is made inoperative pending that review," *id.* at 154.

"The doctrine of exhaustion of administrative remedies is well established in the jurisprudence of administrative law." *McKart*, 395 U.S. at 193. Before bringing an APA challenge in federal court, a plaintiff must exhaust its available administrative remedies. *Idaho Sporting Congress, Inc. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir. 2002) (citing 5 U.S.C. § 704). The APA's exhaustion "requirement applies to claims under NEPA." *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 965 (9th Cir. 2006).

The exhaustion doctrine avoids premature interruption of the administrative process; lets the agency develop the necessary factual background for decisions; gives the agency the first chance to exercise

its discretion and apply its expertise; and avoids judicial interference with the agency until it has completed its action. *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush & Co., Inc.*, 240 F.3d 832, 837 (9th Cir. 2001) (citing *McKart*, 395 U.S. at 193–94); *see also Rittenhouse*, 305 F.3d at 965.

The exhaustion requirement also promotes judicial efficiency because the agency may decide the matter in favor of the plaintiff and obviate the need for judicial review. *McKart*, 395 U.S. at 195. In other words, the exhaustion doctrine allows an agency "to correct its own mistakes" before a court does. *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992). "[E]xhaustion is especially important" in cases where litigants disregard "established agency procedures altogether." *Ass'n of Flight Attendants-CWA, AFL-CIO v. Chao*, 493 F.3d 155, 158–59 (D.C. Cir. 2007).

"There is no bright-line test to determine whether a party has properly exhausted a claim" before a federal agency; "the determination must be made on a case-by-case basis." *Buckingham v. Sec'y of Dep't of Agric.*, 603 F.3d 1073, 1080 (9th Cir. 2010). Exhaustion applies to APA actions "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby*, 509 U.S. at 153.

2. Exhaustion under FDA regulations

FDA regulations require a plaintiff to exhaust its administrative remedies "before any legal action is filed in a court" challenging the

FDA's action or inaction. 21 C.F.R. § 10.45(b). One way a potential plaintiff can satisfy this requirement is to file a citizen petition, which is "[a] request that the Commissioner take or refrain from taking any form of administrative action." *Id.*; *see also id.* § 10.25(a). Any "interested person" can request that the FDA "issue, amend, or revoke a regulation or order," or "take or refrain from taking any other form of administrative action." *Id.* § 10.25(a). After the FDA issues "a final administrative decision based on a petition submitted under § 10.25(a)," the claimant may proceed to court. *Id.* § 10.45.

The citizen-petition requirement applies to all "activities conducted by the [FDA] under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers." *Id.* § 10.1(a). The citizen-petition procedures are well established, and they apply to NEPA claims.

For example, a plaintiff here—the Center for Food Safety (joined by twenty-two other petitioners)—previously used the citizen-petition process to bring NEPA claims before the FDA in another matter challenging the FDA's food-labeling policy for genetically engineered organisms. *See* Petition, Center for Food Safety to FDA, Dkt. No. FDA-2011-P-0723-0001 (Oct. 12, 2011).[2] The Center listed specific actions

[2] Available at https://www.regulations.gov/document?D=FDA-2011-P-0723-0001 (last visited Aug. 11, 2016).

that it wanted the FDA to take, including the rescission of a 1992 policy. *Id.* at 2. And the Center argued that, under NEPA, the FDA should address environmental concerns when making decisions related to labeling and the use of genetic engineering in food. *Id.* at 16. The FDA ultimately rejected the Center's arguments. *See* Petition Denial, FDA to Center for Food Safety, Dkt. No. FDA-2011-P-0723 (Nov. 19, 2015).[3]

Other organizations have filed citizen petitions with the FDA raising NEPA issues. *See, e.g.*, Petition, Earthjustice to FDA, Dkt. No. FDA-2011-P-0448 (June 1, 2011) (requesting, among other things, that the FDA prepare an EIS assessing the environmental impacts of approving an application related to genetically engineered salmon).[4] And the FDA responded to those concerns. *See* Petition Denial, FDA to Earthjustice, Dkt. No. FDA-2011-P-0448 (Nov. 19, 2015) (explaining that the FDA did not need to complete an EIS under NEPA to approve the new animal drug application related to genetically engineered Atlantic salmon).[5]

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[3] Available at https://www.regulations.gov/document?D=FDA-2011-P-0723-0788 (last visited Aug. 11, 2016).

[4] Available at https://www.regulations.gov/document?D=FDA-2011-P-0448-0001 (last visited Aug. 11, 2016).

[5] Available at https://www.regulations.gov/document?D=FDA-2011-P-0448-0004 (last visited Aug. 11, 2016).

After the FDA responds to a citizen petition, the petitioner can file a complaint in federal court. That is, in fact, what Earthjustice did. Joined by two of the plaintiffs in this case—the Center for Food Safety and the Center for Biological Diversity—Earthjustice filed a complaint in federal court challenging the approval of a new animal drug application related to genetically engineered Atlantic salmon. *See* Compl., *Inst. for Fisheries Resources v. Burwell*, No. 16-cv-01574-VC (N.D. Cal. Mar. 30, 2016).

If a petitioner brings suit before the FDA reaches a final administrative decision on a citizen petition, the FDA will seek to dismiss the action or ask for "referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201." *Id.* § 10.45(b).

II. Factual background

When reviewing a district court's order dismissing a complaint, this Court presumes that the alleged facts are true and draws all reasonable inferences in plaintiffs' favor. *Brown v. Elec. Arts, Inc.*, 724 F.3d 1235, 1247 (9th Cir. 2013).

Ractopamine is an animal feed additive that induces faster growth and leaner meat in pigs, cattle, and turkeys. ER 172 (¶27); ER 204 (¶ 35). The FDA first approved ractopamine for use in pigs in 1999 and

later approved its use for cattle and turkeys. ER 174 (¶ 34); ER 205 (¶ 36). According to plaintiffs' complaint, the use of ractopamine:

- presents food safety risks, ER 174–77 (¶¶ 38–48); ER 205–08 (¶¶ 42–54);
- poses human health and environmental risks from manure runoff, ER 178 (¶ 55); ER 208 (¶ 56);
- can be toxic to plants and animals, ER 181–82 (¶¶ 67–71); ER 209 (¶¶ 65–66);
- may, when combined with other animal drugs, have an adverse effect on health, safety, and the environment, ER 182–88 (¶¶ 73–102); ER 210–13 (¶¶ 68–98).

The FDA, plaintiffs allege, has never adequately assessed these environmental issues in a publicly available NEPA document.

Plaintiffs allege that most of the NEPA analysis conducted by the FDA when it approved the use of ractopamine in animal feed "is now more than fifteen years old," and the FDA's analysis "fails to account for significant new circumstances and information relevant to environmental concerns raised" in plaintiffs' complaints. ER 213 (¶ 104); *see also* ER 189 (¶ 108).

III. Procedural background

In 2014, plaintiffs filed complaints to challenge the FDA's approval of new animal drug applications containing ractopamine. ER 166 (¶ 1); ER 198 (¶ 1). Plaintiffs brought suit under the APA

alleging that, when the FDA approved the new animal drug applications containing ractopamine, the FDA failed to conduct environmental analyses required by NEPA. *See* ER 166–67 (¶¶ 3–7); ER 199 (¶¶ 5–6).

Plaintiffs sought declaratory and injunctive relief. They asked the district court to: declare that the FDA's decision to approve the drug applications violated NEPA and the APA; vacate and remand the FDA's approval decisions; and issue preliminary and injunctive relief barring the use of ractopamine-based animal drugs until the FDA complies with NEPA. *See* ER 196; ER 221.

Elanco intervened and moved to dismiss plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state an APA claim. ER 108–14. The district court held a hearing on September 8, 2015. *See* Supplemental Excerpts of Record (SER) 29–56. At the outset, the district court rejected plaintiffs' characterization of the FDA's citizen petition process as "a far-fetched scheme." SER 32; *see also* ER 69. The district court explained that it had reviewed *Association of American Physicians and Surgeons v. FDA*, 539 F. Supp. 2d 21 (D.D.C. 2008), and it questioned whether the citizen petition process was "in fact what the law requires." SER 32.

The district court asked for the FDA's position, noting that the government had not joined Elanco's motion to dismiss plaintiffs' complaints. SER 37. The government explained that "there are

different ways" to construe the complaints. *Id.* On the one hand, plaintiffs seem to have alleged that the FDA failed to analyze environmental impacts under NEPA. *Id.* But that is not all. The government explained that plaintiffs raised allegations based on "changed circumstances or new information," which arose after the FDA had approved the animal drugs. SER 38. For those claims, "the exhaustion requirements are different." *Id.*

Plaintiffs conceded that they did not file a citizen petition with the FDA. SER 44. Since plaintiffs failed to file a citizen petition, the district court wondered how it was "supposed to know FDA's perspective" with respect to the changed circumstances and new information plaintiffs identified. *Id.* After all, the district court explained, it is possible that the FDA may agree with some of plaintiffs' arguments. *Id.*

The district court asked for supplemental briefing addressing the exhaustion of administrative remedies. *See* SER 53–54. The government urged the district court to follow *American Physicians* and require plaintiffs to submit citizen petitions before it considers their NEPA claims. ER 31–38. As in *American Physicians*, the government argued that the APA's exception to the exhaustion doctrine found in 5 U.S.C. § 704 (*i.e.*, an action must be "inoperative" during the agency appeal process) did not apply here because a citizen petition is not an appeal within the agency. ER 35. "Plaintiffs never filed a citizen

petition with FDA," so "they never received a decision on their arguments that could be appealed." *Id.* (citing *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011), *aff'd sub nom.* 664 F.3d 940 (D.C. Cir. 2012)).

Decision under review. The district court granted Elanco's motion and dismissed plaintiffs' complaints. ER 1–16 (reported at 142 F. Supp. 3d 898 (N.D. Cal. 2015)). FDA regulations, the district court explained, require interested parties to file a citizen petition with the FDA before they can seek review of their claims in court. ER 5. Plaintiffs raised three arguments why their failure to exhaust their administrative remedy (*i.e.*, failure to file a citizen petition) did not defeat their claims. ER 6. None had merit.

First, the district court rejected plaintiffs' argument "that NEPA challenges are somehow specially exempt from the APA's clear command requiring administrative exhaustion" simply because, in their view, the Council on Environmental Quality administers NEPA. *Id.*

Second, the district court concluded that that the APA's inoperative requirement from 5 U.S.C. § 704 does not apply to the mandatory citizen-petition requirement. ER 10. A citizen petition, the district noted, "is not an 'appeal to superior agency authority.'" *Id.* n.6 (quoting 5 U.S.C. § 704).

Plaintiffs complained that they did not have an opportunity to participate in the NEPA process, but the district court found otherwise.

"The FDA citizen petition process grants plaintiffs a meaningful opportunity to comment on the FDA approvals, and allows the FDA an opportunity to correct any mistakes it made in the approval process prior to possible judicial intervention." ER 11. Following *Darby*, the district court concluded that it did not have discretion to excuse plaintiffs' failure to exhaust the citizen-petition requirement. ER 12 (citing cases). Assuming it had discretion to waive the exhaustion requirement, the district court analyzed the circumstances of this case and declined to exercise its discretion. ER 13–14.

Finally, the district court held that the government did not waive its challenge to plaintiffs' claims based on failure to exhaust administrative remedies. ER 15. The district court rejected plaintiffs' request to amend their complaints, as plaintiffs "cannot proceed until they exhaust their administrative remedies with the FDA." ER 16.

SUMMARY OF ARGUMENT

A party must first exhaust the mandatory administrative remedies imposed by the FDA before it can seek judicial review of its claims against the agency. Because plaintiffs have not done so, this Court should affirm the dismissal of their complaints.

The exhaustion of administrative remedies doctrine "acknowledges the commonsense notion of dispute resolution that an agency ought to have an opportunity to correct its own mistakes with respect to the programs it administers before it is haled into federal

court." *McCarthy*, 503 U.S. at 145. Plaintiffs offend this longstanding doctrine in contending that they should be allowed to enter federal court without giving the FDA an opportunity to address their claims in the first instance. Plaintiffs' arguments misinterpret precedent, ignore the policies underlying the exhaustion requirement, and otherwise lack any basis in law or fact.

Plaintiffs ask the Court to excuse their failure to file a citizen petition because, in their mistaken view, the FDA can require exhaustion only if it suspends the approval of the relevant new animal drugs while it considers their arguments in the first instance. Plaintiffs misread 5 U.S.C. § 704. The inoperative requirement from Section 704 applies only to administrative appeals required by agency rules. A citizen petition is not an appeal to the FDA's superior agency authority.

The exhaustion of administrative remedies is particularly important in this case because, in the context of new animal drug approvals, a citizen petition provides the first opportunity for interested parties to comment on the FDA's compliance with NEPA.

Parties challenging an agency's compliance with NEPA must alert the agency to their arguments and give the agency the opportunity to respond. *See Vermont Yankee*, 435 U.S. at 553. This Court should require plaintiffs to file a citizen petition so that the FDA can address the new information in their complaints. By skipping the citizen-petition process, plaintiffs have deprived the FDA of both the

opportunity to exercise its expertise over this specific and highly technical subject matter and of the opportunity to generate a useful record for a court to review.

In line with well-established precedent, the district court dismissed plaintiffs' complaints for failure to exhaust their administrative remedies. Even if it did have discretion to waive the exhaustion requirement, the district court did not clearly abuse it.

STANDARD OF REVIEW

"Dismissal for failure to exhaust administrative remedies is a question of law," which this Court reviews de novo. *Farrell v. Principi*, 366 F.3d 1066, 1067 (9th Cir. 2004).

The application of the doctrine of exhaustion of administrative remedies "is within the sound discretion of the district court." *Leorna v. U.S. Dep't of State*, 105 F.3d 548, 550 (9th Cir. 1997). This Court "will not disturb the district court's determination of whether exhaustion is required unless there has been a clear abuse of discretion." *Id.*

This Court "gives great deference to an agency determination regarding NEPA requirements." *Auburn v. U.S. Gov't*, 154 F.3d 1025, 1037 (9th Cir. 1998). The Court cannot substitute its judgment for that of the FDA when it assesses the environmental consequences of its actions. *Ass'n of Pub. Agency Customers v. Bonneville Power Admin.*, 126 F.3d 1158, 1183 (9th Cir. 1997).

ARGUMENT

I. Plaintiffs failed to exhaust their administrative remedies because they did not file a citizen petition with the FDA

The district court correctly dismissed plaintiffs' complaints for failure to exhaust their administrative remedies. FDA regulations require that a party first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action," and that request must "be the subject of a final administrative decision based on [the citizen petition] . . . before any legal action is filed in a court." 21 C.F.R. § 10.45(b). It is undisputed that plaintiffs did not file a citizen petition before bringing suit. *See* Appellants' Br. 17.

A. Section 704's inoperative requirement does not apply to citizen petitions filed with the FDA

Citing 5 U.S.C. § 704 and *Darby v. Cisneros*, 509 U.S. 137 (1993), plaintiffs suggest that they need not comply with administrative exhaustion requirements unless the action they contest is inoperative during the pendency of their challenge. *See* Appellants' Br. 18–19. In their view, the FDA can require exhaustion only if it suspends the approval of animal drugs containing ractopamine during the pendency of their citizen petition. Plaintiffs' argument misinterprets precedent and misconstrues the FDA's citizen petition process.

1. Section 704 requires plaintiffs to exhaust their administrative remedies

"A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.SC. § 702. Section 702 "provides the general right to judicial review of agency actions under the APA." *Darby*, 509 U.S. at 146.

Section 704 "establishes when such review is available." *Id.* Section 704, "by its very terms, has limited the availability of the doctrine of exhaustion of administrative remedies to that which the statute or rule clearly mandates." *Id.* In full, Section 704 states:

> Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

5 U.SC. § 704.

At the outset, an agency action is final "and therefore 'subject to judicial review' under the first sentence [of Section 704]," "[w]hen an aggrieved party has exhausted all administrative remedies expressly

prescribed by statute or agency rule." *Darby*, 509 U.S. at 146 (quoting 5 U.SC. § 704).

Section 704 also says that an agency action is "final" without regard to whether the aggrieved party has sought any form of reconsideration or made an appeal to superior agency authority, unless a statute expressly provides otherwise *or* the agency has, by rule, required the aggrieved party to appeal to superior agency authority and has provided that the agency action is inoperative during the appeal. *See Darby*, 509 U.S. at 146–47, 154.

Plaintiffs contend that "the district court fundamentally misinterpreted the plain language of § 704." Appellants' Br. 17. But plaintiffs' contention rests on a cribbed reading of the statutory language and it was interpreted in *Darby*. *See id.* at 16–20 (focusing solely on Section 704's inoperative requirement for an appeal to superior agency authority). Plaintiffs misinterpret Section 704 by ignoring important context and detail from *Darby* as well as the cases from this Court and others requiring plaintiffs to file a citizen petition with the FDA before invoking the jurisdiction of the federal courts.

Even before *Darby*, this Court applied "the traditional exhaustion requirement" to a party seeking to challenge the FDA's classification of a dietary supplement as a food additive. *Dietary Supplement Coal., Inc. v. Sullivan*, 978 F.2d 560, 564 (9th Cir. 1992). The district court dismissed the plaintiffs' complaint in that case because they failed to

file a citizen petition with the FDA and, therefore, did not exhaust their administrative remedies. *Dietary Supplement Coal., Inc. v. Sullivan*, 796 F. Supp. 441, 446 (D. Or. 1991). This Court affirmed the dismissal, rejecting the plaintiffs' attempt to bypass agency expertise before "invoking the jurisdiction of the federal courts." *Dietary Supplement Coal.*, 978 F.2d at 564.

Following *Darby*, courts have consistently held that a plaintiff's failure to file a citizen petition with the FDA is a failure to exhaust an administrative remedy. *See, e.g.*, *Holistic Candlers*, 770 F. Supp. 2d at 163, *aff'd sub nom.* 664 F.3d 940; *Am. Physicians*, 539 F. Supp. 2d. at 21–24, *aff'd* 358 F. App'x 179, 180–81 (D.C. Cir. 2009) (the district court correctly concluded that the plaintiffs "failed to exhaust their administrative remedies" after they failed to file a "citizen petition with FDA") (per curiam); *Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969–70 (10th Cir. 2011) ("Cody's failure to avail itself of available administrative remedies [*i.e.*, file a citizen petition] defeats its claim."). Plaintiffs brush aside these cases.

2. Section 704's inoperative requirement applies only to appeals to superior agency authority

Plaintiffs insist that they did not have to file a citizen petition because the petition would not have rendered the FDA's animal drug approvals inoperative. Appellants' Br. 20–22. Yet plaintiffs overlook that Section 704's inoperative requirement applies only to

administrative *appeals* required by agency rules; "a citizen petition is not an appeal to superior agency authority." *Id.* at 26.

In fact, FDA's regulations require plaintiffs to file a citizen petition in the first instance, but the regulations do not require plaintiffs to pursue an administrative appeal before going to court. "An interested person may request judicial review of a final decision of the Commissioner in the courts *without first petitioning the Commissioner for reconsideration* or for a stay of action," subject to limitations not relevant here. 21 C.F.R. 10.45(e) (emphasis added).

The inoperative requirement does not apply to an aggrieved party's obligation to exhaust available administrative remedies by raising its grievances to the agency (*i.e.*, filing a citizen petition) in the first instance. *See Darby*, 509 U.S. at 146 (requiring an aggrieved party to exhaust "all administrative remedies expressly prescribed by . . . agency rule" before seeking judicial review). "[T]he exhaustion doctrine continues to exist under the APA to the extent it is required by statute or *by agency rule* as a prerequisite to judicial review." *Id.* at 153 (emphasis added).

FDA regulations explicitly require plaintiffs to exhaust their administrative remedies—*i.e.*, file a citizen petition under 21 C.F.R. § 10.25—"before any legal action is filed in a court" challenging the FDA's action or inaction. 21 C.F.R. § 10.45(b). Plaintiffs never filed a

citizen petition with the FDA, Appellants' Br. 17, so they cannot seek judicial review of their grievances, *see Darby*, 509 U.S. at 146.

Neither *Darby* nor Section 704 says anything about whether an aggrieved party's *initial challenge* must render an agency's action inoperative. Section 704's "inoperative" language applies only when an agency requires an appeal to superior agency authority. Indeed, "[t]he last sentence of [Section 704] refers explicitly to 'any form of reconsideration' and 'an appeal to superior agency authority.'" *Darby*, 509 U.S. at 146 (quoting 5 U.S.C. § 704). By its plain language, Section 704 permits an agency to "avoid the finality of an initial decision, first, by adopting a rule that an agency appeal be taken before judicial review is available, and, second by providing that the initial decision would be 'inoperative' *pending appeal*." *Id.* at 152 (quoting 5 U.S.C. § 704) (emphasis added).

Put another way, Section 704 allows an agency "to require by rule that in such cases parties who are dissatisfied with the 'initial' decisions of hearing officers must appeal to the agency before seeking judicial review, but only if the agency further provides that the hearing officers' decisions shall be *inoperative pending such administrative appeals*." U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act 104 (1973) (emphasis added).

Plaintiffs suggest that the district court erred when it relied on *American Physicians* to dismiss their complaints. *See* Appellants'

Br. 24. They claim that the D.C. Circuit never addressed Section 704's inoperative requirement when it affirmed the district court's decision. *See* Appellants' Br. 24 n.5. There was, however, no need for the court to do so. Neither the district court nor the D.C. Circuit needed to address Section 704's inoperative requirement because it does not apply when a plaintiff has failed to initiate agency review in the first instance. Far from demonstrating that the district court erred when it relied on *American Physicians*, plaintiffs' argument confirms that the district court's decision fits comfortably within this precedent.

In fact, the D.C. Circuit has addressed Section 704's inoperative requirement, and it distinguished cases in which parties fail to initiate an *initial* administrative review from cases in which they have failed to initiate administrative *appeals*. *See DSE, Inc. v. United States*, 169 F.3d 21, 26–27 (D.C. Cir. 1999). A party can seek judicial review without pursuing a discretionary intra-agency appeal when the initial agency decision is not rendered inoperative by the pending appeal. *Id.* at 27 (applying *Darby* and 5 U.S.C. § 704). But that party still needs to file "an initial . . . protest" with the agency to exhaust its administrative remedies before "it can proceed in the federal courts seeking relief under the APA." *Id.* Unlike the plaintiffs in this case, the appellant in *DSE* "did just that," so its claim was properly before the court. *Id.* Plaintiffs' claims were not.

Plaintiffs reject the straightforward interpretation of Section 704's inoperative requirement and argue that it must apply to the FDA's citizen petition process to foreclose judicial review. Plaintiffs point to this Court's decision in *Idaho Watersheds Project v. Hahn*, 307 F.3d 815 (9th Cir. 2002) (*Idaho Watersheds II*), *abrogated on other grounds by Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7 (2008), *as recognized in Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), to support their argument. However, plaintiffs' reading of *Idaho Watersheds II* falls apart upon inspection because that case applies the inoperability requirement to administrative *appeals* and is thus fully consistent with our argument here.

The environmental groups in *Idaho Watersheds II* "did not exhaust their administrative *appeals*." *Id.* at 825 (emphasis added). The Court therefore had to consider whether the administrative *appeal* regulations from the Bureau of Land Management (BLM) "provide[d] procedures that effectively render[ed] inoperative the challenged decision pending appeal." *Id.* If BLM's procedures rendered the initial decision inoperative during the pending appeal, the Court recognized that the "exhaustion of administrative appeals" would bar judicial review. *Id.* Under the unique facts of the case, "BLM's regulations render[ed] the decision 'inoperative' in name only," so the Court held that administrative exhaustion was not required. *Id.* at 827–28.

Because a citizen petition filed with the FDA will not automatically render the new animal drug approvals inoperative, plaintiffs suggest that *Idaho Watersheds II* supports judicial review in this case. Appellants' Br. 20–22. But context matters. Plaintiffs ignore important differences between this case and the unique circumstances in *Idaho Watersheds II*.

The applicable 1997 regulations required BLM "to consult with affected parties, issue a proposed decision, consider any protests, and turn the proposed decision into a final decision." *Idaho Watersheds Project v. Hahn*, 187 F.3d 1035, 1036 (9th Cir. 1999). The environmental groups challenging BLM's decision had previously participated in the agency's decision-making process by challenging BLM's initial proposed decision. *See* Plaintiffs-Appellees' Responding Brief 9 n.6, *Idaho Watersheds*, 2001 WL 34094626, 187 F.3d 1035 (9th Cir. 1999). The environmental groups had "submitted protests and comments to BLM on the proposed 1997 permits *before* they were finalized." *Id.* (emphasis added). Because of that participation, the environmental groups argued that they had "exhausted all administrative proceedings necessary before coming into federal court." *Id.*

This Court agreed. *See Idaho Watersheds II*, 307 F.3d at 829. Even though one of the environmental groups, the Idaho Watersheds Project, had dismissed its administrative appeal, it had previously

participated in BLM's initial decision-making process by protesting the proposed decision. The dismissal meant that BLM's decision became final; "the agency's decision making process *was* completed, and the agency decision was *not* subject to being modified or reversed." *Id.* (emphasis in original).

The other environmental groups failed to file "any administrative appeals." *Id.* But that was irrelevant because both environmental groups had previously "challenge[d] all the permits" by submitting protests and comments to BLM before it finalized its actions. *Id.* Both groups could therefore proceed in federal court. *See id.*

The circumstances in this case differ from those in the *Idaho Watersheds* litigation. Here, plaintiffs "were not provided any opportunity to participate" in the FDA's decision-making process when it approved the applications for the new animal drugs. Appellants' Br. 4–5. That is because the Trade Secret Act, 18 U.S.C. § 1905, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), prohibit the FDA from disclosing environmental information during the drug approval process. *See* 21 C.F.R. § 25.50(b). Even so, the FDA complies with NEPA "to the fullest extent possible," 42 U.S.C. § 4332, because it discloses environmental information at the earliest possible time (in general, after it approves a drug).

The citizen-petition process provides plaintiffs with the first opportunity to challenge the FDA's compliance with NEPA. *See* 21

C.F.R. §§ 10.25, 10.45(b). The environmental groups in *Idaho Watersheds* exhausted their administrative remedies at the first opportunity because they submitted protests and comments to BLM before the agency finalized the grazing permits. Here, even though the drug approvals are final, the district court correctly recognized that the citizen petition process nonetheless gives "plaintiffs a meaningful opportunity" to challenge the FDA's consideration of environmental impacts under NEPA when the agency approved the relevant animal drugs. ER 11.

Plaintiffs do not grapple with the nuances of the *Idaho Watersheds* cases. Nor do plaintiffs appreciate the impact of BLM's unique regulations governing administrative appeals for grazing permits. To the extent that some district courts have applied Section 704's inoperative requirement to initial agency decision making (*i.e.*, "whether a stay of the agency decision is a true stay"), these courts have done so only in the context of BLM's unique grazing regulations. *See* Appellants' Br. 21 (quoting *Eason Land Co.. LLC v. Dep't of Interior*, No. 14-cv-00951-SU, 2015 WL 1538501, at *10 (D. Or. Apr. 7, 2015), and *Or. Nat. Desert Ass'n v. BLM*, No. 10-cv-01331-SU, 2014 WL 4832218, at *12 (D. Or. Sept. 29, 2014)); *see also Mont. Wilderness Ass'n v. Fry*, 310 F. Supp. 2d 1127, 1138–39 (D. Mont. 2004); *San Juan Citizens' All. v. Babbitt*, 228 F. Supp. 2d 1224, 1232–33 (D. Colo. 2002); *Or. Nat. Desert Ass'n v. Green*, 953 F. Supp. 1133, 1141–42 (D. Or.

1997); *Wilderness Workshop v. BLM*, No. 08-cv-00462-REB-MEH, 2008 WL 1897997, at *1–2 (D. Colo. Apr. 28, 2008).

These cases do not support plaintiffs' argument because, even in the unique context of the BLM grazing regulations, courts have not allowed a plaintiff to skip into federal court without first raising its arguments before the agency. For example, in *Eason Land*, the district court held that the plaintiffs had failed to exhaust their administrative remedies after they "elected not to challenge the BLM's decision by lodging a protest or filing an appeal or stay petition." 2015 WL 1538501, at *9.

Plaintiffs in this case stretch Section 704 beyond recognition by suggesting that they can get into federal court without first filing a citizen petition to challenge the FDA's actions. This Court should not allow plaintiffs to circumvent the FDA's review process by leapfrogging into federal court. Like it did with the BLM in the *Idaho Watersheds* litigation, the Court should give the FDA the opportunity to address plaintiffs' arguments in the first instance before allowing them to proceed in federal court.

B. Requiring plaintiffs to file a citizen petition with the FDA will fulfill the purposes of the exhaustion doctrine

The doctrine of exhaustion of administrative remedies "serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency." *McCarthy*, 503 U.S. at 145. "The

doctrine cuts down on the work of the courts, preserves integrity and autonomy of the administrative process, and ensures that when the administrative proceeding does come before the court, the court will have before it the mature, considered, and final articulation of the basis of the agency's action." *Glisson v. U.S. Forest Serv.*, 55 F.3d 1325, 1326–27 (7th Cir. 1995).

Plaintiffs gloss over the purposes of the exhaustion doctrine. *See* Appellants' Br. 47–49. The citizen-petition process, in their myopic view, will not enhance judicial efficiency because there is already an administrative record associated with the FDA's approval of the challenged new animal drugs. *Id.* 48. The district court rejected this argument, *see* ER 8, 13–14, and this Court should too.

Requiring plaintiffs to file a citizen petition with the FDA will "ensure that the agency possessed of the most expertise" has the "first shot at resolving [plaintiffs'] difficulties," and it will prevent federal courts from addressing "premature claims." *Rittenhouse*, 305 F.3d at 965. Exhaustion is particularly important where, as here, allowing plaintiffs "to proceed in federal court would deprive the agency of *any* opportunity to exercise its discretion or apply its expertise." *Ass'n of Flight Attendants-CWA*, 493 F.3d at 159 (emphasis in original).

As the district court rightly recognized, there is no way "to know FDA's perspective" in this case because plaintiffs *never* filed a citizen petition, as required by agency regulations. SER 44. Had plaintiffs

filed a citizen petition, the FDA could have corrected any alleged errors in its NEPA analysis "before it is haled into federal court." *McCarthy*, 503 U.S. at 145. Even if the citizen petition process did not resolve the controversy, it could still "produce a useful record for subsequent judicial consideration, especially in a complex or technical factual context" like this one. *Id.*

Plaintiffs have deprived the FDA of both the opportunity to "exercise its expertise" over the specific and highly technical subject matter and of the opportunity to generate a useful record. *Buckingham*, 603 F.3d at 1080 (quoting *United Farm Workers v. Ariz. Agric. Emp't Relations Bd.*, 669 F.2d 1249, 1253 (9th Cir. 1982)).

C. Plaintiffs must file a citizen petition with the FDA so the agency can consider their NEPA claims

Even if this Court disagrees that the exhaustion doctrine applies to plaintiffs' claims that the agency's NEPA analysis was arbitrary, capricious, or otherwise not in accordance with the law, the Court should still require plaintiffs to file a citizen petition so that the FDA can address new information from their complaints.

"[W]hile it is true that NEPA places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action," plaintiffs also have a duty to alert the FDA of their "positions and contentions." *Vermont Yankee*, 435 U.S. at 553. "Persons challenging an agency's compliance with NEPA must

'structure their participation so that it . . . alerts the agency to the [parties'] position and contentions,' in order to allow the agency to give the issue meaningful consideration." *Pub. Citizen*, 541 U.S. at 764 (quoting *Vermont Yankee*, 435 U.S. at 553)).

In a run-of-the-mill case, the agency informs the public that it addressed environmental concerns in its decision making, and any interested party can then participate in the process by commenting on the agency's analysis. *See, e.g.*, *Balt. Gas & Elec. Co.*, 462 U.S. at 97–98 & n.11.

In the context of drug approvals, the citizen petition provides the first opportunity for interested parties to comment on the FDA's compliance with NEPA. *See* 21 C.F.R. §§ 10.25, 10.45. The FDA discloses environmental information at the earliest possible time, but it cannot generally disclose information during the pre-approval process. *See* 21 C.F.R. § 25.50(b). Amici err in suggesting otherwise. *See* Professors' Br. 4–5. That is because Congress requires the FDA to safeguard drug manufacturers' confidential business information. *See* 18 U.S.C. § 1905; 21 U.S.C. § 331(j).

Plaintiffs must file a citizen petition so that the FDA has an opportunity to give their claims meaningful consideration. *See Pub. Citizen*, 541 U.S. at 764. According to plaintiffs, their complaints merely allege that the FDA failed to consider environmental information that the agency either knew or should have known. *Id.*

Plaintiffs, however, defeat their own argument, as their complaints belie this assertion.

Plaintiffs challenge the FDA's approval of "eighteen ractopamine-based animal drugs," Appellants' Br. 4 (citing ER 188–89, 191–92, 213, 216), and suggest that the FDA relied on information that "is now more than fifteen years old," ER 213 (¶ 104); *see also* ER 189 (¶ 108). In their own words, the agency's NEPA analysis "fail[ed] to account for significant *new* circumstances and information relevant to environmental concerns." ER 213 (¶ 104) (emphasis added); *see also* ER 189 (¶ 108).

At the time of the relevant drug approvals, plaintiffs contend that the environmental information from their complaints was either "already in front of the [FDA]" or it was "so obvious" that plaintiffs "need not be required to point it out." Appellants' Br. 48. Plaintiffs never explain how that is possible.

Take, for example, some of the studies that plaintiffs cite in their complaints. In the context of alleging that the FDA did not assess the food safety, health, and environmental effects of ractopamine (a drug first approved in 1999), plaintiffs refer to:

- adverse events in pigs through March 2011, ER 206 (¶ 45);
- an unnamed 2009 study, ER 175 (¶ 42); ER 206 (¶ 46);
- a 2003 study published in the Journal of Animal Science, ER 177 (¶ 51);

- an article published in 2008; ER 178 (¶ 55);
- the number of pigs, turkey, and cattle slaughtered in the U.S. in 2013, ER 179 (¶¶ 57–59);
- a 2012 report from the Environmental Protection Agency, ER 208 (¶ 60); and
- emerging scientific data from an article published in 2009, ER 180 (¶ 62).

Even if the Court presumes the validity of the alleged facts and draws all reasonable inferences in plaintiffs' favor, *Elec. Arts*, 724 F.3d at 1247, plaintiffs have not explained how, or in what context, the FDA failed to consider information and documents published after it first approved ractopamine in 1999.

Requiring plaintiffs to file a citizen petition will ensure that the issues of concern to plaintiffs are raised "with sufficient clarity to allow the decision maker to understand and rule on the issue raised." *Nat'l Parks & Conservation Ass'n v. BLM*, 606 F.3d 1058, 1065 (9th Cir. 2009) (quoting *Great Basin Mine Watch*, 456 F.3d at 968)).

To the extent plaintiffs allege that the new information published after 1999 amounts to an extraordinary circumstance that would have precluded the FDA's use of a categorical exclusion, *see* 21 C.F.R. § 25.21, this argument cuts in favor of requiring a citizen petition. If plaintiffs believe that such information was available when the FDA reviewed

certain approvals (post-1999), plaintiffs should have alerted the FDA in a citizen petition.

To the extent plaintiffs allege that the FDA should have known about the new circumstances and information at the time of approval, this argument also cuts in favor of requiring a citizen petition. By filing a citizen petition, plaintiffs can raise the new information and give the FDA the opportunity to address their claims in the first instance.

In their prayer for relief, plaintiffs focus on Topmax, a new animal drug "comprised entirely of ractopamine." ER 213 (¶ 100). Plaintiffs allege that the FDA violated NEPA when it approved Topmax in 2008 because the agency allegedly failed to take a "hard look" at the environmental impacts in the Topmax EA completed in 2001 and a 2003 FONSI. ER 194 (¶¶ 129–31); ER 218–19 (¶¶ 130–38). Yet the majority of the above-cited articles, documents, and studies came *after* the FDA approved Topmax in 2008.

Plaintiffs further fault the FDA's use of categorical exclusions for combination drugs approved after 2008. *See* ER 195 (¶¶ 132–35); ER 219–21 (¶¶ 139–49). Even these claims are based on new information. Plaintiffs allege that the FDA "failed to at least prepare supplemental EAs in light of significant *new circumstances* that arose *since the original approvals*." ER 221 (¶ 148) (emphasis added); *see also* ER 195 (¶ 133). The original approvals for the combination drugs occurred many years ago. *See* ER 173 (¶ 31) (1999 for ractopamine);

ER 182 (¶ 73) (1961 for tylosin); ER 185 (¶ 85) (1970 for monensin); ER 187 (¶ 95) (1968 for melengestrol).

Requiring plaintiffs to submit a citizen petition would give the FDA the opportunity to resolve their claims and correct any alleged errors before judicial intervention. *Zara v. Ashcroft*, 383 F.3d 927, 931 (9th Cir. 2004) (citing *Sagermark v. INS*, 767 F.2d 645, 648 (9th Cir. 1985)). By requiring a citizen petition, this Court will also give "deference to Congress' delegation of authority" to agencies because it will allow the FDA "to apply its special expertise" in the first instance. *McCarthy*, 503 U.S. at 145.

Plaintiffs claim that, if this Court requires them to file a citizen petition, it will frustrate the purposes of exhaustion and NEPA. *See* Appellants' Br. 29; *see also* Professors' Br. 11–16. This argument misses the mark. Agencies certainly cannot employ a "[p]ost-hoc examination of data to support a pre-determined conclusion," *Sierra Club v. Bosworth*, 510 F.3d 1016, 1026 (9th Cir. 2007), but there is no evidence to suggest that will occur here.

On the contrary, the FDA has considered arguments raised by plaintiffs in other contexts. *See* Petition Denial at 1, FDA to Center for Food Safety, Dkt. No. FDA-2011-P-0723 (Nov. 19, 2015) (denying petitioner's request that FDA "require that foods that are genetically engineered organisms . . . be labeled."). The FDA considered the Center's arguments and explained that the Center had failed to provide

sufficient information to support its claims. *Id.* at 19. Plaintiffs may not like the outcome, but the FDA did not engage in a post-hoc analysis to support its pre-determined conclusion.

Plaintiffs contend that this Court would create a never-ending "treadmill of exhaustion" if it required them to file a citizen petition with the FDA. Appellants' Br. 25. That is also incorrect. Plaintiffs understand how the process works: they have to file a citizen petition that provides the FDA with a chance to address their arguments before they file a lawsuit.

Plaintiffs are familiar with the process. After the FDA denied a citizen petition in 2015, *see* Petition Denial, FDA to Earthjustice, Dkt. No. FDA-2011-P-0448 (Nov. 19, 2015), the petitioner filed a complaint in district court, *see* Compl., *Inst. for Fisheries Resources*, No. 16-cv-01574 (N.D. Cal. Mar. 30, 2016), raising some of the same arguments previously raised in its citizen petition. Plaintiffs-Appellants Center for Food Safety and the Center for Biological Diversity are plaintiffs in that litigation.

Nor is there any merit to plaintiffs' argument that the citizen petition is a "separate" administrative process from the FDA's approval of the challenged new animal drugs. *See* Appellants' Br. 27–28. The citizen petition allows the FDA to consider new evidence and potentially withdraw the approval of an animal drug based on that evidence. Even if the citizen petition is separate, that is an immaterial distinction

because "the crucial consideration" is whether the review "may completely wipe away [the] prior decision." *Cabaccang v. INS*, 627 F.3d 1313, 1316 (9th Cir. 2010). The FDA's citizen petition process could lead to withdrawing the animal drug approvals, and thus is required as part of administrative exhaustion.

II. Assuming the district court had discretion to waive the administrative exhaustion requirement, it did not abuse that discretion when it dismissed plaintiffs' complaints

The district court recognized that, following *Darby*, some courts have suggested that they cannot excuse the failure to exhaust mandatory administrative remedies expressly provided by agency rules in APA cases. ER 12 (citing *Volvo GM Heavy Truck Corp. v. U.S. Dep't of Labor*, 118 F.3d 205, 212 (4th Cir. 1997); *Conservation Force v. Salazar*, 919 F. Supp. 2d 85, 90–91 (D.D.C. 2013)). The district court found these cases persuasive and concluded that it did not have discretion to waive the FDA's citizen-petition requirement. *Id.*

Plaintiffs identified cases suggesting otherwise, *see* ER 39–42, which, in their view, the district court ignored, Appellants' Br. 36. Following *Darby*, plaintiffs point out that some courts have concluded that they have discretion, in certain circumstances, to excuse the failure to exhaust mandatory administrative remedies provided by agency rules in APA cases. *See* Appellants' Br. 35–36 (citing cases). That includes some cases in the context of the FDA's citizen-petition

requirement. *See, e.g.*, *Cody Labs.*, 446 F. App'x at 969; *Am. Physicians*, 539 F. Supp. 2d at 23–24.

This Court has not yet addressed this issue directly. Either way, the Court should affirm the dismissal of plaintiffs' complaints. Assuming the citizen petition requirement was "subject to judicial waiver," the district court considered whether: (1) the FDA could grant effective relief through the administrative process; (2) requiring the administrative remedy would result in undue prejudice to plaintiffs if they had to delay judicial review; and (3) exhaustion would be futile because the FDA is biased or has otherwise predetermined the issue. ER 13 (citing *McCarthy*, 503 U.S. at 146–49).

The district court rejected plaintiffs' arguments and refused "to excuse plaintiffs' failure to exhaust in this case." *Id.* This conclusion must stand, as the district court's decision was not "a clear abuse of discretion." *Leorna*, 105 F.3d at 550.

A. FDA can grant plaintiffs appropriate relief through the citizen petition process

Courts may waive administrative exhaustion if there is "some doubt as to whether the agency was empowered to grant effective relief," *McCarthy*, 503 U.S. at 147, but that circumstance does not exist here. Contrary to plaintiffs' argument, the FDA can grant plaintiffs appropriate relief.

The district court correctly explained that the FDA can initiate withdrawal proceedings based on a citizen petition. *See* ER 14 (citing 21 U.S.C. § 360b(e)(1)). Plaintiffs reject that reading and suggest that Section 360b allows the FDA only to withdraw an animal drug based on safety concerns, not environmental concerns. *See* Appellants' Br. 41–42. Even if that is correct, plaintiffs allege that the new animal drugs present food safety risks, ER 174–77 (¶¶ 38–48); ER 205–08 (¶¶ 42–54), and that the new animal drugs pose human health and environmental risks from manure runoff, ER 178 (¶ 55); ER 208 (¶ 56), which the FDA has never adequately assessed.

In any event, to the extent the scientific evidence FDA evaluates as part of an environmental review supports a determination about whether the animal drug is safe under the Federal Food, Drug, and Cosmetic Act, the FDA may rely on the scientific evidence in an action to withdraw a drug approval. FDA's regulations on public participation for an EIS state:

> Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form the basis for the Agency to consider beginning an action *to withdraw the approval* or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.

21 C.F.R. § 25.52(b) (emphasis added). FDA regulations do not specifically state that the agency will consider withdrawing drug approvals based on comments submitted in relation to an environmental review, but the FDA may rely, as appropriate, on the scientific evidence it receives in an environmental review to evaluate the safety of a new animal drug. *See* 21 U.S.C. § 360b(e).

Even if the FDA's ability to act on a citizen petition is limited only to revisiting NEPA analyses and not to withdrawing new animal drug approvals, the purposes of exhaustion would still be served by requiring plaintiffs to initiate a citizen petition. *See Bailey v. Avilla R-XIII Sch. Dist.*, 721 F.3d 588, 595 (8th Cir. 2013) ("[W]here some of the relief the Plaintiffs seek is available . . . and exhaustion would not be futile, the inadequate remedy exception to the exhaustion requirement does not apply."). Although an "administrative action may in some sense be futile," the administrative exhaustion requirement is not. *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1115 (9th Cir. 2003). That is because "[t]here is no doubt that an administrative record would provide clarification and would help resolve the [plaintiffs'] claims in court." *Id.* at 1115–16; *see also McCarthy*, 503 U.S. at 145–46.

Here, the district court noted that judicial review would be limited because "the FDA has not yet developed an administrative record, utilizing its specialized expertise," to address plaintiffs' allegations. ER 13. The district court did not clearly abuse its discretion when it

concluded that the "citizen petition process is the appropriate procedural mechanism for plaintiffs to raise [their] contentions in the first instance, before seeking judicial review." ER 13–14.

Because the FDA can provide plaintiffs adequate relief and because a court would not likely, at this point and with this limited record, be able to provide any further remedies beyond those the FDA could provide, no waiver of exhaustion for inadequate relief is warranted.

B. Plaintiffs cannot establish undue prejudice

If required to file a citizen petition, plaintiffs cannot establish undue prejudice. *See McCarthy*, 503 U.S. at 146–47. Plaintiffs argue that prejudice would result from an "unreasonable or indefinite timeframe for administrative action," Appellant's Br. 38 (quoting *McCarthy*, 503 U.S. at 147), but they have failed to make their case.

First, plaintiffs cannot show that the FDA will unreasonably delay its response to their citizen petition. Plaintiffs point to delays from other citizen petitions and to statistics summarizing the types of petitions delayed more than fifteen years ago, Appellant's Br. 39 & n.9, but that is not enough to establish that the FDA will unreasonably delay responding to a petition that plaintiffs have yet to file.

It would be particularly inappropriate for a court to waive exhaustion requirements for delay when the party seeking review has never filed anything with the agency. *See Ass'n of Flight Attendants-*

CWA, 493 F.3d at 159 (refusing to waive exhaustion requirement for a claimant that did not initiate administrative procedures; "having largely disregarded agency procedures the unions are in no position to complain of agency delay").

Administrative proceedings can take time. Plaintiffs' argument "that the pursuit of administrative remedies may be time consuming" is an "insufficient justification for bypassing agency expertise and invoking the jurisdiction of the federal courts." *Dietary Supplemental Coal.*, 978 F.2d at 564; *see also, e.g., Maxon Marine, Inc. v. Dir., Office of Workers' Comp. Programs*, 39 F.3d 144, 147 (7th Cir. 1994) ("[D]elay is not a valid ground for bypassing . . . a mandatory resort to such administrative remedies as remain open to the aggrieved party, unless those remedies are palpably inadequate . . . , resulting in serious injustice."). The Fourth Circuit, for example, refused to waive exhaustion after an agency's seven-year delay in bringing an administrative enforcement action, stating that a determination that the delay was "unreasonable" would "require a fact-intensive inquiry that cannot take place before the administrative process has concluded." *Volvo GM Heavy Truck Corp.*, 118 F.3d at 214.

The district court did not clearly abuse its discretion when it found that "plaintiffs' claims of injustice" were not compelling, "given that they waited until November 2014 to file these lawsuits challenging FDA approvals issued beginning in 2008." ER 13.

C. A citizen petition would not be futile

Plaintiffs have failed to show that "exhaustion would be futile, meaning that nothing could be gained from permitting further administrative proceedings." *Anderson v. Babbitt*, 230 F.3d 1158, 1164 (9th Cir. 2000).

A showing of futility requires more than just initial indications that the agency's position may be adverse to the claimants. *See City of Oakland, Cal. v. Hotels.com LP*, 572 F.3d 958, 962 (9th Cir. 2009), *as amended* (Aug. 20, 2009) ("[W]e reject the City's characterization that exhaustion would be futile because the position of the parties is already 'clear.' The issue in this case is not the 'positions' of the parties but rather the actual tax liability.").

Futility requires a showing that an agency ruling against the claimant is not merely the likeliest outcome, but that it is a certainty. *Marine Mammal Conservancy v. Dep't of Agric.*, 134 F.3d 409, 413 (D.C. Cir. 1998); *Smith v. Blue Cross & Blue Shield United of Wisconsin*, 959 F.2d 655, 659 (7th Cir. 1992). There is no such certainty here. Plaintiffs provide "nothing but speculation to suggest that the [FDA] would have reached a preconceived result." *Diaz v. United Agr. Employee Welfare Ben. Plan & Trust*, 50 F.3d 1478, 1485–86 (9th Cir. 1995). That is not enough.

Plaintiffs base their accusations of bias on an FDA environmental safety review document, in which the FDA "admits that 'as long as [a

drug] sponsor claims a categorical exclusion, cites the correct CFR code, and states that to their knowledge no extraordinary circumstances exist,' it will grant a categorical exclusion 'regardless of whether extraordinary circumstances exist.'" Appellant's Br. 45 (quoting ER 61). Since the district court did "not have a sufficient record in front of it," it correctly refused to speculate "whether any dereliction of duty has occurred." ER 14.

The district court found that plaintiffs failed to show "that the FDA letter constitutes a final position, or that the FDA has predetermined that it will not engage in further NEPA analysis where a citizen petition demonstrates that doing so is appropriate." *Id.* Indeed, the court determined that "the prudent course" is "to allow the FDA its opportunity to resolve plaintiffs' grievances administratively." *Id.*

In any event, the letter generally tracks FDA's regulation on categorical exclusions:

> A person submitting an application or petition of a type subject to categorical exclusion . . . is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant's knowledge, no extraordinary circumstances exist.

21 C.F.R. § 25.15. A single document that largely restates agency regulations falls far short of proving that the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider," which would be required for a showing of futility. *James v.*

U.S. Dep't of Health & Human Servs., 824 F.2d 1132, 1139 (D.C. Cir. 1987).

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(e)(1), requires the FDA to consider comments and new information that come to light after drugs have been approved. Further, 21 C.F.R. § 25.52 states that comments on an EIS for certain actions, including approvals for new animal drugs, can form the basis for the agency to consider an action to withdraw the approvals for new animal drugs. Plaintiffs have provided no reason for any court to believe that the FDA would neglect its regulatory and statutory duties if plaintiffs properly raised their claims in a citizen petition.

Plaintiffs cannot show that the FDA has predetermined the outcome of its administrative proceedings. *See Citadel Sec., LLC v. Chicago Bd. Options Exch., Inc.*, 808 F.3d 694, 700 (7th Cir. 2015) ("While there is no obvious path to the monetary compensation plaintiffs seek, it is impossible to say whether relief is available since plaintiffs have made no attempt to bring the matter before the SEC."); *see also Am. Physicians*, 539 F. Supp. 2d at 24 ("[T]here is no indication that the administrative process would be futile because the agency has not yet had the opportunity to address all of plaintiffs' arguments.").

The district court found that plaintiffs failed to prove bias, citing the lack of a fully articulated administrative record and the fact that plaintiffs had not shown "that the FDA has predetermined that it will

not engage in further NEPA analysis where a citizen petition demonstrates that doing so is appropriate." ER 14. Plaintiffs point out that an administrative record already exists, Appellants' Br. 46, but that does nothing to refute the district court's reasoning. An administrative record may exist for the drug approvals, but plaintiffs challenge the NEPA review by raising new evidence, which the agency allegedly has not considered. The FDA deserves an opportunity to apply its expertise to plaintiffs' particular claims—many of which are scientific and technical—through the citizen-petition process before being hauled into court.

The district court, far from abusing its discretion, reasonably determined that no prudential reasons exist to deny the FDA an opportunity to address plaintiffs' grievances. Its finding that there are no circumstances warranting waiver of exhaustion is entirely consistent with the purposes of exhaustion: "to allow the administrative agency in question to exercise its expertise over the subject matter and to permit the agency an opportunity to correct any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or premature judicial intervention into the administrative process." *Buckingham*, 603 F.3d at 1080.

This Court interpreted the Supreme Court's statement that an environmental review's "flaws might be so obvious that there is no need for a commentator to point them out," *Pub. Citizen*, 541 U.S. at 765, to

mean that, if an agency had independent knowledge of the substantive issues that a claimant seeks to raise, exhaustion is not required, *see Barnes*, 655 F.3d at 1132; *'Ilio'ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1092–93 (9th Cir. 2006).

Plaintiffs claim that, because the FDA knew that it was relying on older environmental analyses, the independent knowledge exception to exhaustion should apply. Appellants' Br. 48–49. But to warrant an exhaustion waiver, the agency's independent knowledge needs to equate to an obvious flaw in the environmental review. Plaintiffs have not established that the "environmental information that was already in front of the Agency—or the lack thereof," Appellant's Br. 48, rendered the NEPA review so obviously flawed that they did not need to raise this information with the agency.

In cases where this Court has concluded that independent knowledge constituted an obvious flaw in the NEPA process, it has primarily been instances in which the agency entirely failed to consider an important impact or alternative. *See Barnes*, 655 F.3d at 1132–35 (obvious flaw when the agency, despite having independent knowledge that a new airport runway may lead to increased plane traffic, failed to consider potential impacts of increased plane traffic in an EIS); *Friends of Clearwater v. Dombeck*, 222 F.3d 552, 558–59 (9th Cir. 2000) (obvious flaw when the agency failed to consider significant new information of which it had independent knowledge).

Plaintiffs advance only conclusory statements that FDA was "aware of the superficial nature" of its review, Appellants' Br. 48, and have failed to establish that FDA did something so obviously flawed as completely ignoring an impact of which it had independent knowledge.

CONCLUSION

This Court should affirm the district court's dismissal of plaintiffs' complaints for failure to exhaust their administrative remedies. Assuming the district court could have waived the exhaustion requirement, it did not clearly abuse its discretion when it declined to do so.

Respectfully submitted,

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August 12, 2016
DJ # 90-1-4-14326

STATEMENT OF RELATED CASES

Attorneys for the federal Defendants-Appellees are not aware of any related cases as defined in Ninth Circuit Rule 28-2.6.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,427 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

I certify that this brief 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 I prepared it using Microsoft Word in a proportionally-spaced typeface, Century Schoolbook 14-point.

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CERTIFICATE OF SERVICE

I certify that, on August 12, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. All case participants registered as CM/ECF users will be served by the CM/ECF system.

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