No. 15-17510

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, *et al.*,

Plaintiffs-Appellants,

v.

MARGARET HAMBURG, *et al.*,

Defendants-Appellees,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
Consolidated Case Nos. 14:14-cv-04932-YGR, 4:14-cv-04933-YGR

PLAINTIFFS-APPELLANTS' OPENING BRIEF

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May 10, 2016

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Plaintiffs-Appellants Center for Food Safety, Center for Biological Diversity, Animal Legal Defense Fund, Humane Society of the United States, Sierra Club, and United Farm Workers of America hereby certify that they have no parent corporations, and that no publicly held corporation owns more than ten percent of any of the Plaintiff-Appellant organizations.

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INTRODUCTION

In this case, six public interest organizations whose missions include protecting human health, animal health, and the environment, challenge final decisions by Appellee U.S. Food and Drug Administration (FDA or the Agency) to approve eighteen animal drugs containing ractopamine hydrochloride (ractopamine) without adherence to the statutory requirements of the National Environmental Policy Act (NEPA). Ractopamine belongs to a class of animal drugs known to cause significant harm to farm animals and the environment. The use of ractopamine and the drugs with which it is combined exacerbate the already significant environmental damage posed by industrial livestock production. Plaintiffs-Appellants (Appellants) were denied the opportunity to challenge FDA's final agency actions in district court because the court wrongly decided that Appellants failed to exhaust administrative remedies. The district court's error is the subject of this appeal.

JURISDICTION

This appeal arises from a judgment and order entered by the United States District Court for the Northern District of California, which had jurisdiction under 28 U.S.C. § 1331. Final judgment was issued on November 19, 2015. Excerpts of

Record (ER) 021.[1] Appellant appealed on December 18, 2015. ER017-20. The appeal is from a final judgment and this Court has jurisdiction under 28 U.S.C. § 1291.[2]

ISSUES PRESENTED

1. Whether the district court erred when it held that Appellants were required to file a citizen petition before seeking judicial review of FDA's failure to comply with NEPA in approving animal drug applications, even though a citizen petition would not render the drug approvals inoperative pending the Agency's review or constitute an appeal to superior agency authority, as the Administrative Procedure Act (APA) requires for regulatory exhaustion procedures to apply, and the drug approvals were already the subject of final administrative decisions based on petitions as defined in 21 C.F.R. § 10.25(a) and therefore immediately reviewable?

2. Whether the district court erred when it held that it did not have discretion to waive FDA's citizen petition provision even though the provision is

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[1] "ER" refers to the documents in the Excerpts of Record. The number corresponds to the Excerpts' consecutive, Bates-stamped page numbers.

[2] Pertinent statutes and regulations are set forth in the addendum to this brief.

nonjurisdictional, because it does not meet the APA's criteria for agency-created administrative exhaustion requirements?

3. Whether the district court abused its discretion by requiring Appellants to comply with FDA's citizen petition provision despite that: Appellants will be irreparably harmed by the indefinite time period provided FDA to respond to citizen petitions; the petition process does not empower FDA to grant the relief requested by Appellants; petitioning would be futile because the Agency has predetermined the issues before it; and the petition process would not serve the purposes of exhaustion in this case?

STATEMENT OF THE CASE

This case is about whether FDA's animal drug approvals—specifically, eighteen ractopamine approvals—are insulated from judicial review unless an approval is first the subject of a citizen petition. Ractopamine is a controversial, non-therapeutic animal drug manufactured by Elanco and other veterinary drug companies. It is one of more than 450 animal drugs that FDA has approved for use in livestock, many of which promote animal growth and suppress the negative effects that heavily-concentrated confinement has on animals raised for food. 21 C.F.R. pts. 520, 522, 558. By FDA's own accounts, ractopamine has caused more harm to animals than any other animal drug currently available. ER175, 206. Dozens of countries, including China and all member nations of the European

Union, have restricted or banned ractopamine use. ER173, 198, 205. Nevertheless, FDA has approved its use for the more than one billion pigs, turkeys, and beef cattle that are raised for food each year in the United States. ER198, 214-18.

At issue in this case are FDA's decisions to approve eighteen ractopamine-based animal drugs without adequately analyzing and disclosing their environmental impacts under NEPA. ER188-89, 191-92, 213, 216. Ractopamine causes significant environmental impacts, *see, e.g.*, ER178-82, 208-09, both as a result of the harm it causes animals, ER175-6, 184, 206-7, 210, and independently when released into the environment, *see, e.g.*, ER178-83, 185, 208-12. NEPA requires FDA to analyze the direct, indirect, and cumulative effects of each additional approved use when approving these drugs. ER202. FDA failed to do so. ER177-78, 181-82, 184, 187-91, 193-94, 208-9, 211-17.

The animal drug approval process under the Federal Food, Drug, and Cosmetic Act (FFDCA) is a closed-door process in which Appellants—environmental, public health, animal protection, and farm worker advocacy groups whose members are injured by FDA's approvals[3]—were not provided any

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[3] *See, e.g.*, ER154-55 (Ms. Whitefoot fishes for salmon in a river polluted by manure runoff containing ractopamine); ER142, 144, 146 (Mr. Callicrate, an independent cattle rancher, is at a competitive disadvantage because he raises and sells cattle free of animal drugs); ER124, 126-28 (Ms. Crouch is a biologist concerned about harm to endangered species); ER133-34 (Ms. Smoldt is concerned

opportunity to participate. *See* 21 C.F.R. §§ 10.40(e)(3), 10.20(j)(2)(i), 20.61. Instead, Appellants only became aware of each approval after FDA published notice of its final decision approving each drug or drug combination in the Federal Register. These drug approvals constitute final agency actions for the purposes of judicial review. *See* 21 U.S.C. § 360b(i).

In order to obtain information about FDA's final approvals and its compliance with NEPA, Appellants Animal Legal Defense Fund and Center for Food Safety filed Freedom of Information Act (FOIA) requests in March 2012 and February 2013. Only after Appellants filed litigation to compel record production did FDA begin releasing documents—in April 2014—that, for the first time, alerted Appellants to the severity of FDA's NEPA violations in approving each drug. *See* ER047; *see* Compl., *Animal Legal Def. Fund v. FDA*, No. 13-04622 (N.D. Cal. filed Oct. 7, 2013), ECF No. 1; Joint Case Management Statement at 2, *Animal Legal Def. Fund v. FDA*, No. 13-04622 (N.D. Cal. filed Apr. 5, 2015), ECF No. 28 ("Defendant began producing documents to Plaintiffs on a periodic, rolling basis on Tuesday, April 15, 2014.").

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for her own health because she lives in an area where antibiotic-resistant bacteria are prevalent); ER117-18 (United Farm Workers of America is deeply concerned with negative impacts of drugs that are used in animal production facilities where farmworkers are employed, and near where farmworkers live).

Appellants are harmed by the individual and cumulative impacts of ractopamine and ractopamine-based animal drugs on human, animal, and environmental health, which FDA failed to adequately analyze. *See generally* ER165-96, 197-222. As a result, on November 6, 2014, Appellants challenged FDA's final agency actions approving all eighteen new animal drug applications pursuant to the APA and NEPA. Intervenor-Appellee Elanco (Elanco), a ractopamine manufacturer, was allowed to intervene. *See* ER158-59.

On June 9, 2015, Elanco moved to dismiss Appellants' claims under Federal Rule of Civil Procedure 12(b)(6). Elanco argued that Appellants were required to file a citizen petition under 21 C.F.R. § 10.25(a)(2) to alert FDA to its failure to comply with its statutory obligations under NEPA before seeking judicial review of FDA's final drug approvals. ER108-114. That the animal drug approvals were already the subject of final administrative decisions based on petitions as defined in 21 C.F.R. § 10.25(a)(1) and therefore immediately reviewable, and that FDA's citizen petition process does not satisfy the requirements for administrative exhaustion set forth in the APA, 5 U.S.C. § 704, was completely overlooked by Elanco.

FDA did not join in Elanco's motion to dismiss. At the hearing on the motion to dismiss, counsel for FDA represented that "if [Appellants are] just challenging the NEPA analysis that was completed as being inadequate, or

arbitrary and capricious, then we believe that the administrative remedies in that case have been exhausted and they would be able to bring those claims." ER045-6. FDA later changed its position and argued that Elanco's motion to dismiss should be granted. ER032, 34.

On November 5, 2015, the district court dismissed Appellants' claims for failure to exhaust administrative remedies. ER001-16. The court agreed with Elanco and held that Appellants were required to file a citizen petition before seeking judicial review of the animal drug approvals, because it claimed a "citizen petition process is the appropriate procedural mechanism for plaintiffs to raise [their] contentions in the first instance." ER013-14. In doing so, the district court ignored that Appellants' challenge was to eighteen separate final agency actions with corresponding administrative records for the court to review, while a citizen petition is an entirely new administrative process that, under the APA, cannot serve as a bar to judicial review of previously-decided final agency actions. The court further found that it could not excuse Appellants' failure to submit a citizen petition before seeking judicial review of the drug approvals, ER012-13, even though, among other deficiencies, a citizen petition cannot provide Appellants the relief requested in their Complaints pursuant to NEPA.

Appellants timely appealed. ER017-20.

STATUTORY AND REGULATORY BACKGROUND

National Environmental Policy Act

NEPA is "our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a). The twin pillars of NEPA are the requirements that agencies (1) carefully evaluate the environmental impacts of major federal actions *before* undertaking the action, and (2) fully advise the public of the potential impacts of those actions. *Id*. § 1500.1.

In a NEPA analysis, the federal agency—here, FDA—must identify the direct, indirect, and cumulative impacts of the proposed action and consider alternative actions and their impacts before making an irreversible and irretrievable commitment of resources. 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1508.7, 1508.8, 1502.14. "Impacts" include ecological, aesthetic, historic, cultural, economic, social, or health—a wide range of potential effects on the quality of the human environment. 40 C.F.R. § 1508.8. NEPA also requires agencies to evaluate economic or social and natural or physical environmental effects that are interrelated. *Id*. § 1508.14.

> NEPA procedures must insure that environmental information is available to public officials and citizens *before* decisions are made and before actions are taken. The information must be of high quality. Accurate scientific analysis, expert agency comments, and public scrutiny are essential to implementing NEPA.

Id. § 1500.1(b) (emphasis added).

Federal Food, Drug, and Cosmetics Act and FDA Regulations

The FFDCA governs the use of all animal drugs. 21 U.S.C. § 360b. In order to legally sell an animal drug, the drug manufacturer must petition FDA for approval in the form of a New Animal Drug Application, requesting FDA to issue a regulation authorizing and prescribing lawful conditions for the drug's use. 21 U.S.C. § 360b(b)(1); 21 C.F.R. § 10.25(a)(1). FDA's approval of an animal drug is a final agency action, published in the Federal Register, and effective immediately as a regulation under the FFDCA. 21 U.S.C. § 360b(i); *see also, e.g.*, New Animal Drugs for Use in Animal Feeds; Ractopamine; Tylosin, 74 Fed. Reg. 66,914 (Dec. 17, 2009) (final rule implementing FDA approval of supplemental new animal drug application of tylosin combined with ractopamine for use in pigs).

In approving an animal drug, FDA analyzes the drug's effects on human and animal health. 21 C.F.R. § 514.1; 21 U.S.C. § 360b(e). Once FDA approves a drug, the FFDCA allows FDA to withdraw or suspend approval for an animal drug only if there are questions about the drug's safety or effectiveness with regard to the health of man or target animals—not to the environment. *See* 21 U.S.C. § 360b(e)(1). Hence, FDA is required to comply with NEPA and assess the effects of a drug on the environment *prior* to approving it. 21 C.F.R. §§ 514.1(b)(14), 25.1 ("All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other

statutory requirements."). FDA is not required to engage in notice-and-comment rulemaking to issue new animal drug regulations, *id.* § 10.40(e)(3), and is exempt from public disclosure of drug-related information, *see id.* §§ 10.20(j), 20.61. Thus, FDA typically does not make public its approval and corresponding NEPA determination until the Agency has taken final action.

FDA regulations also provide for a separate "citizen petition" process, which is distinct from the animal drug application and approval process. An interested person may petition the FDA Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action by filing a citizen petition under 21 C.F.R. § 10.30. FDA's decision to grant or deny a citizen petition is a separate final agency action subject to judicial review. *Id*. § 10.30(e)(2)(i)-(ii), (e)(3).

The Administrative Procedure Act

The APA provides judicial review of agency action. 5 U.S.C. § 702. "Agency action" is defined to include "the whole or a part of any agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." *Id.* § 551(13). "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." *Id.* § 704.

Under § 704's plain terms:

> Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of [§ 704], 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.

Id. Thus, unless exhaustion is required by statute, two requirements must be met to prevent an agency decision from becoming "final" and subject to judicial review: the agency regulations must (1) require an appeal of the challenged action to a superior agency authority, and (2) provide that the challenged action is inoperative until the agency makes a final decision on the appeal. *Id*.

The legislative history of § 704 underscores Congress's intent to require that agency rules requiring administrative appeals must render the initial decision inoperative pending appeal. The judiciary committee explained:

> [A]n agency may permit an examiner to make the initial decision in a case, which becomes the agency's decision in the absence of an appeal to or review by the agency. If there is such review or appeal, the examiner's initial decision becomes inoperative until the agency determines the matter. For that reason this subsection [§ 704] permits an agency also to require by rule that, if any party is not satisfied with the initial decision of a subordinate hearing officer, the party must first appeal to the agency (*the decision meanwhile being inoperative*) before resorting to the courts. *In no case may appeal to 'superior agency authority' be required by rule unless the administrative decision meanwhile is inoperative*, because otherwise the effect of such a requirement would be to subject the party to the agency action and to repetitious administrative process without recourse. There is a fundamental

> inconsistency in requiring a person to continue "exhausting" administrative processes after the administrative action has become, and while it remains, effective.

S. Rep. No. 752, 79th Cong., at 213 (1945) (emphases added). In a 1945 letter to the Judiciary Committee, the Attorney General explained:

> The last sentence [of § 704] makes clear that the doctrine of exhaustion of administrative remedies with respect to finality of agency action is intended to be applied only (1) where expressly required by statute . . . or (2) where the agency's rules require that decisions by subordinate officers must be appealed to superior agency authority before the decision may be regarded as final for purposes of judicial review.

Id. at 230. In 1947, the Attorney General confirmed that the last clause of § 704:

> [P]ermits 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 in original); *see also id.* at 104-05 (an agency may impose a requirement to appeal to superior agency authority, "but only, as in the case of required appeals from hearing officers' initial decisions, if the agency's decision is inoperative pending such appeal.").

SUMMARY OF THE ARGUMENT

The district court's conclusion that Appellants must file a citizen petition as a prerequisite to judicial review of FDA's final agency actions is contrary to the APA and controlling Supreme Court precedent. 5 U.S.C. § 704; *Darby v. Cisneros*, 509 U.S. 137 (1993). APA § 704 provides for review of final agency actions—here, the animal drug approvals. FDA can only create an exception to finality by promulgating exhaustion regulations that meet two criteria. First, the underlying agency actions—the animal drug approvals—must be inoperative pending the appeal. Second, the regulations must actually create a process by which the interested person appeals to "superior agency authority." A citizen petition does not render animal drug approvals inoperative, nor is it an appeal to superior agency authority. A citizen petition is an entirely new administrative action. Thus, FDA's citizen petition regulations do not comply with APA § 704 and cannot stand as an obstacle to judicial review.

Should this Court conclude that FDA's citizen petition provision does create a regulatory exhaustion hurdle, the provision is nevertheless nonjurisdictional and therefore, the district court had the discretion to waive Appellants' compliance with it. The district court abused its discretion by ordering Appellants to file a citizen petition despite the futility in requiring Appellants to do so.

STANDARD OF REVIEW

This Court reviews de novo the district court's dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). *Lacey v. Maricopa Cty.*, 693 F.3d 896, 911 (9th Cir. 2012). No deference is owed the district court. *See Barrientos v. Wells Fargo Bank, N.A.*, 633 F.3d 1186, 1188 (9th Cir. 2011). The Court must accept "all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1159 (9th Cir. 2012) (citation omitted).

The district court's decision not to excuse compliance with a nonjurisdictional administrative exhaustion provision is reviewed for an abuse of discretion. *See Pinhas v. Summit Health, Ltd.*, 894 F.2d 1024, 1031 (9th Cir. 1989), *aff'd*, 500 U.S. 322 (1991). In determining whether the district court abused its discretion, this Court is required "first to consider whether the district court identified the correct legal standard for decision of the issue before it." *U.S. v. Hinkson*, 585 F.3d 1247, 1251 (9th Cir. 2009). The district court's interpretation of the legal principles underlying the application of its discretion is a question of law subject to de novo review. *Korab v. Fink*, 797 F.3d 572, 577 (9th Cir. 2014) (citations omitted). The district court necessarily abused its discretion if it based its ruling on an erroneous view of the law. *Id.* An exercise of discretion that is based

on an erroneous interpretation of the law can be freely overturned. *In re Arden*, 176 F.3d 1226, 1228 (9th Cir. 1999).

ARGUMENT

I. The District Court Erred in Holding that Appellants Were Required to File a Citizen Petition Before Obtaining Judicial Review of FDA's Final Agency Actions.

The Supreme Court has repeatedly held that the purpose of the APA is to remove obstacles to judicial review of agency action. *Bowen v. Mass.*, 487 U.S. 879, 904 (1988) (citing *Shaughnessy* v. *Pedreiro*, 349 U.S. 48, 51 (1955)); *see also Darby*, 509 U.S. at 146-47) (citations omitted). Congress intended the APA's judicial review provisions to cover a "broad spectrum of administrative actions," and that the APA's "'generous review provisions' must be given a 'hospitable' interpretation." *Bowen*, 487 U.S. at 904 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 140-141 (1967) (footnote omitted)). Only on "a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." *Abbot Labs*., 387 U.S. at 140-41 (citing *Rusk v. Cort*, 369 U.S. 367, 379-380 (1962)).

There is no doubt that animal drug approvals constitute reviewable final agency actions.[4] Drug companies, including Elanco, submitted petitions under 21 C.F.R. § 10.25(a) and FDA made final administrative decisions on those petitions. *Stauber v. Shalala*, 895 F. Supp. 1178, 1188 (W.D. Wis. 1995) ("[T]he secretary's decisions on new drug applications constitute final agency action for purposes of exhaustion.") (citing 21 C.F.R. §§ 10.25, 10.45).

These decisions are subject to judicial review without any additional administrative process unless administrative exhaustion is required by statute or agency rule. 5 U.S.C. § 704. The parties and the district court agree that the FFDCA does not require administrative exhaustion for drug approvals. The Agency can still require exhaustion of administrative remedies by rule, but only if two conditions are met: (1) the rule requires an appeal to superior agency authority, *and* (2) the appeal renders the underlying agency decision inoperative. *Id.* Citizen petitions do not render drug approvals inoperative pending FDA review, nor is a citizen petition an appeal to superior agency authority. Thus, FDA's regulations do not satisfy the requirements for administrative exhaustion that Congress

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[4] This issue was not in dispute in the proceedings below. *See* ER161 ("The case involves review of final agency determination [sic] under the Administrative Procedure Act . . . and therefore does not present any disputed genuine issues of material fact.")

established in the APA, and filing a citizen petition is not required prior to obtaining judicial review of FDA's final agency actions approving ractopamine.

Notwithstanding the APA's generous review provisions and the criteria for regulatory exhaustion set out in § 704, the district court concluded that Appellants were required to file a citizen petition before challenging eighteen separate animal drug approvals as violating NEPA. In holding that FDA's citizen petition provision could stand as a prerequisite to judicial review of FDA's final decisions to approve these drugs, the district court fundamentally misinterpreted the plain language of § 704. FDA's decisions are final agency actions that are immediately subject to judicial review. 5 U.S.C. § 704. FDA's citizen petition regulations cannot stand as a bar to review of these actions because the regulations do not render the drug approvals inoperative pending the agency's review of the citizen petition, nor require an appeal to superior agency authority. Further, a post-decision citizen petition in the NEPA context will frustrate both the purpose of exhaustion and the goals of NEPA. Appellants are not required to submit a citizen petition before obtaining judicial review of the drug approvals for failure to comply with NEPA.

A. FDA's Citizen Petition Provision Does Not Satisfy the APA's Statutory Requirements for Exhaustion Prior to Review of Final Agency Actions Because It Does Not Render Drug Approvals Inoperative Pending Review.

FDA's citizen petition procedure cannot be construed as an exhaustion requirement under the statutory requirements of the APA. The APA limits an

agency's ability to require an administrative appeal by rule to rules that render the underlying decision "meanwhile . . . inoperative." 5 U.S.C § 704. FDA's citizen petition regulations have no such provision; filing a citizen petition does not render the underlying agency decision inoperative pending agency review of the petition. Accordingly, Appellants cannot be required to file a citizen petition before seeking judicial review.

The fundamental error the district court made in this regard was holding that *Darby* is limited to optional administrative remedies. The Supreme Court in *Darby* unequivocally stated that, in order to serve as a prerequisite to judicial review, agency regulations prescribing exhaustion procedures must require that both an appeal be taken and that the challenged "action meanwhile is inoperative." *Darby*, 509 U.S. at 154. This was not limited to optional remedies.

In *Darby*, an administrative law judge (ALJ) barred developers from participating in a federal program with the Department of Housing and Urban Development (HUD) for eighteen months because the developers engaged in a faulty insurance scheme. *Id.* at 141. The developers chose not to seek further administrative review of the ALJ's decision and instead sought judicial review. *Id.* at 142. HUD attempted to argue that the developers, by forgoing the option to seek review by the Secretary of HUD, had failed to exhaust their administrative remedies. *Id*. Thus, the Supreme Court considered whether "federal courts have the

authority to require a plaintiff to exhaust available administrative remedies before seeking judicial review under the APA, where neither the relevant statute nor agency rules specifically mandate exhaustion as a prerequisite to judicial review." *Id.* at 138.

The Court held that the APA's language is explicit: "an appeal to 'superior agency authority' is a prerequisite to judicial review only when 'expressly required by statute' or when the agency requires an appeal 'by rule and provides that the [administrative] action is . . . inoperative' pending that review." *Id*. at 137. Since neither the statute nor regulations at issue in *Darby* mandated an appeal to the HUD Secretary, the decision was "final agency action" subject to judicial review under the APA.

Despite *Darby*'s clear holding, Elanco and the district court both misinterpreted *Darby* as stating that the "'inoperative' exception only applies to *optional* administrative remedies." ER010 (citing *Darby*, 509 U.S. at 146). The district court quoted language where the Court was explaining that under the APA, courts are not free to apply the prudential doctrine of administrative exhaustion where § 704 has "limited the availability of exhaustion of administrative remedies to that which the statute or rule clearly mandates." *Darby* , 509 U.S. at 146; ER010. But in context, this language cannot be read as the Court implicitly holding that the inoperative language only applies to optional administrative remedies. This

misinterpretation ignores the plain language of the APA and the Court's clear statements elsewhere in the opinion that "where the APA applies, an appeal to 'superior agency authority' is a prerequisite to judicial review only when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review." *Id.* at 154. *Darby* made perfectly clear that agencies could only avoid the finality of a decision by first "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. "Otherwise, the initial decision becomes final, and the aggrieved party is entitled to judicial review." *Id*.

Ninth Circuit precedent supports this conclusion. *See Idaho Watersheds Project v. Hahn*, 307 F.3d 815 (9th Cir. 2002), *abrogated on other grounds by Winter v. Natural Res. Def. Council, Inc*., 555 U.S. 7 (2008), as *recognized in Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010). In *Idaho Watersheds*, environmental groups challenged the Bureau of Land Management's (BLM's) decision to issue sixty-eight grazing permits in violation of NEPA and other federal statutes and regulations. *Id.* at 822. BLM contended that the decision to issue the permits was not final and that the environmental groups had failed to exhaust their administrative remedies. *Id*. at 823. In considering BLM's exhaustion defense, the court noted that "[i]f [BLM's administrative appeal] regulations do not

allow for the decision to be rendered inoperative pending administrative appeal, then exhaustion of administrative appeals is not required and the matter was properly before the district court." *Id.* at 825. The court went on to hold that the environmental groups were not required to exhaust administrative remedies because "in this case the BLM's regulations do not allow for the agency decision to be rendered inoperative pending administrative appeal." *Id*. at 835.

The court in *Idaho Watersheds* did not require plaintiffs to exhaust even though the BLM regulations allowed a party to petition for a stay of the decision pending appeal. *Id*. Two district courts have analyzed the APA and the *Idaho Watersheds* opinion, and both agree that: "whether exhaustion is required under [*Idaho Watersheds*] hinges on whether a stay of the agency decision is a true-stay—i.e., whether it actually stops the harm alleged to flow from the proposed action." *Eason Land Co. v. Dept. of Interior*, No. 14-00951, 2015 WL 1538501, at *10 (D. Or. Apr. 7, 2015) (citing *Or. Natural Desert Ass'n v. BLM*, No. 10-01331, 2014 WL 4832218, at *12 (D. Or. Sept. 29, 2014)); *see also Darby*, 509 U.S. at 154.

Here, filing a citizen petition will not stay or otherwise delay any FDA administrative action. 21 C.F.R. § 10.35(d). While separate FDA regulations allow interested parties to request a stay of an administrative action, the stay is entirely discretionary, and rests on FDA making each of four findings: (1) the petitioner

will suffer irreparable harm, (2) the petitioner is pursuing the case in good faith, (3) the petitioner has supported sound public policy grounds, and (4) the delay resulting from the stay is not outweighed by public health or other interests. *Id.* § 10.35(e) (stating that the Commissioner of FDA shall grant a stay "if *all* of the following apply") (emphasis added). The Commissioner is free to balance any interests with those of the petitioner. *Id.* ("The Commissioner may grant a stay in any proceeding if it is in the public interest and the interest of justice."); *id.* § 10.35(e)(4) (allowing the Commissioner to balance "other public interests"). The Commissioner also determines the time period of any stay he implements. *See id.* § 10.35(e). And, only if FDA exercises its discretion to grant a stay will the challenged actions be rendered inoperative. Despite the serious and irreparable harms Appellants alleged in their Complaints, *see*, *e.g.*, ER175-87, 205-13, FDA has asserted in this litigation that Appellants do not meet the stay criteria. ER036 (claiming that Appellants "can hardly complain of irreparable harm," one of the required findings that empowers FDA to grant a stay). Nothing in the APA or *Darby* allows the Agency to block judicial review indefinitely while it determines whether it will render the underlying decision inoperative on a case-by-case basis.

Courts in this Circuit and elsewhere have found that a discretionary stay provision such as FDA's does not function as an administrative exhaustion requirement under APA § 704 because it does not render the Agency's decision

inoperative. *Mont. Wilderness Ass'n v. Fry*, 310 F. Supp. 2d 1127, 1139 (D. Mont. 2004) (holding exhaustion not required "[b]ecause the appeal regulations do not . . . automatically stay a decision pending appeal"); *Or. Natural Desert Ass'n v. Green*, 953 F. Supp. 1133, 1141-42 (D. Or. 1997) (regulations requiring aggrieved party to request a stay, vesting discretion in agency to grant or deny a stay, are inconsistent with the APA's "unequivocal" requirement that exhaustion render the action inoperative); *San Juan Citizens' All. v. Babbitt*, 228 F. Supp. 2d 1224, 1233 (D. Colo. 2002) (same).

Further, only judicial review can give Appellants the remedies sought in this case: immediately vacating the approvals and removing the drugs from the market. Requiring Appellants to file a citizen petition without a corresponding mandatory stay subjects them to continued harm pending FDA's indefinite review of the citizen petition. Elanco and other drug companies will continue to sell the animal drugs in question, and livestock facilities will continue to release these drugs into the environment. Environmental harm—the same harm that FDA was required to analyze before it approved the eighteen animal drugs—will amplify over the course of FDA's review. "There is a fundamental inconsistency in requiring a person to continue 'exhausting' administrative processes after the administrative action has become, and while it remains, effective." S. Rep. No. 752 at 213. This inconsistency is further compounded by the confidential nature of the animal drug

approvals. Appellants were forced to file FOIA requests and FOIA litigation to uncover evidence of FDA's NEPA violations; they should not then be required to file a citizen petition to alert the Agency of its violations when all the while the ractopamine approvals are valid.

Finally, Elanco and FDA both relied on *Association of American Physicians & Surgeons, Inc. v. FDA* (*American Physicians*), 539 F. Supp. 2d. 4 (D.D.C. 2008), below, to support their position that Appellants were required to exhaust by filing a citizen petition. ER027-28, 34-6, 56, 111-12. *American Physicians* is not binding on, nor should it be persuasive to, this Court because the decision does not address the second requirement of the APA: that a regulation mandating appeal to superior agency authority must also render the otherwise final agency action inoperative. 539 F. Supp. 2d. at 21-22.[5]

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[5] The United States Court of Appeals for the District of Columbia Circuit subsequently affirmed *American Physicians* in an unpublished decision, but it similarly did not address the fact that FDA's citizen petition regulations do not render underlying decisions inoperative. *Ass'n of Am. Physicians & Surgeons v. FDA (American Physicians II)*, 358 Fed. Appx. 179, 181 (D.C. Cir. 2009). Moreover, the courts' discussion on exhaustion in both cases was dicta, because both courts held that plaintiffs there lacked standing. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (The Supreme Court has repeatedly emphasized that "[w]ithout jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.") (internal quotation omitted).

FDA's citizen petition process does not render animal drug approvals inoperative pending review of a citizen petition. Thus, a citizen petition is not required.

B. FDA's Citizen Petition Provision Does Not Satisfy the APA's Statutory Requirements for Exhaustion Prior to Review of Final Agency Actions Because a Citizen Petition Is Not an Appeal to Superior Agency Authority.

Even if FDA's citizen petition provision did render animal drug approvals inoperative pending review of a citizen petition—they do not—the provision still does not comply with the plain language of the APA because a citizen petition is neither an appeal from an initial agency decision, nor will a superior agency authority hear it. The district court agreed: "the limitations in section 704 could not excuse [P]laintiffs' failure to exhaust because *the citizen petition is not an 'appeal to superior agency authority.'*" ER010 (citing 5 U.S.C. § 704) (emphasis added). A citizen petition is a brand new administrative proceeding, used to request that FDA issue, amend, or revoke an order, or take or refrain from taking some form of administrative action. 21 C.F.R. § 10.30(b)(3)(A); *see also id.* § 10.25 (entitled "Initiation of administrative proceedings"). If a citizen petition could be considered an appeal to superior agency authority, a petitioner would have to submit a new citizen petition to seek agency review of a decision on a prior citizen petition. This would create a neverending treadmill of exhaustion and cannot be the result that

FDA intended. Because a citizen petition is not an appeal to superior agency authority, it is not required prior to obtaining judicial review.

Congress spoke directly to the effect of an administrative appeal on the finality of agency action in § 704 of the APA:

> Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of [§ 704] 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.S.C. § 704. By its plain language, the APA limits an agency to requiring exhaustion by an appeal to "superior agency authority," and nothing else. *Id*. The introductory sentence—"except as otherwise required by statute"—means that Congress, by statute, can expressly require seeking or obtaining a "declaratory order," or "any form of reconsideration" before an agency action is final and judicially reviewable. In contrast, an agency rule cannot preclude finality simply by requiring, seeking, or obtaining declaratory relief, reconsideration, or other relief. This is because APA § 704 separates with the word "or" its description of how *statutes* may preclude an action's finality and how an *agency rule* can. Basic principles of statutory construction establish that the use of "or" to join two terms indicates that the terms have different meanings. *See United States v. Arreola*, 467 F.3d 1153, 1157 (9th Cir. 2006) ("As a matter of grammatical construction, the use

of the disjunctive indicates that Congress was addressing two separate acts."). This difference in § 704 must be given effect. *Webb v. Smart Document Sols., LLC*, 499 F.3d 1078, 1084 (9th Cir. 2007) ("The canon of statutory construction *expressio unius est exclusio alterius* . . . 'creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.'") (citations omitted). Finally, if Congress intended to allow an agency to require exhaustion by rule with other procedural constructs, such as "any form of reconsideration," it would have listed them. *Khatib v. Cty. of Orange*, 639 F.3d 898, 902 (9th Cir. 2011) ("We presume that Congress 'says in a statute what it means and means in a statute what it says there.'") (citing *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992)).[6]

The district court glossed over this statutory construction and required a citizen petition even though the court acknowledged it is not an "appeal to superior agency authority." ER010 (quoting 5 U.S.C. § 704). In doing so, the district court did not reconcile the inherent conflict in requiring Appellants to file an entirely

[6] The legislative history bolsters the plain language of the APA limiting exhaustion by regulation to an "an appeal to superior agency authority." An agency may "permit an examiner to make the initial decision." S. Rep. No. 752 at 213. This decision becomes the agency's final decision in a case where there is no appeal. However, APA § 704 permits an agency to require, by rule, that if any party is not satisfied with the initial decision of a subordinate hearing officer, the party must first appeal to the agency. *Id*. This is what Congress intended by an "appeal to superior agency authority." *Id.*; *see also Darby*, 509 U.S. at 147-48.

new administrative proceeding in which FDA's determination is a separate final agency action that is immediately subject to judicial review, *see* 21 C.F.R. § 10.45(a), (d), (e), when Appellants' challenge is to a complete administrative process that has already harmed Appellants. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (discussing finality of agency action). Thus, a citizen petition initiating new agency action is not an "appeal to superior agency authority" of FDA's prior existing, and otherwise final, agency decisions—here, its decision to approve the ractopamine drug applications without adherence to NEPA. Appellants were not required to file a citizen petition to seek review of FDA's failure to comply with NEPA in approving ractopamine drug applications.

The district court's ruling therefore requires Appellants to comply with a FDA-created regulatory procedure that does not meet the requirements of 5 U.S.C. § 704: it does not render FDA's decisions inoperative pending administrative appeal, nor require an appeal to superior agency authority. The decision, in effect, trumps the APA and controlling Supreme Court and Ninth Circuit precedent, and grants FDA authority that Congress did not intend: to insulate its final actions from judicial review, even while such an actions are irreparably injuring affected parties. FDA's citizen petition provision therefore cannot and does not apply as a bar to Appellants' claims here.

C. Requiring Appellants to Submit a Citizen Petition Before Seeking Judicial Review of Final Agency Actions Frustrates the Purposes of Exhaustion and NEPA.

Requiring Appellants to file a citizen petition would frustrate the fundamental purposes of both the exhaustion doctrine and NEPA. APA § 704 and NEPA have the same underlying goal: to prevent agencies from implementing decisions before interested persons and the general public have had an opportunity to vet those agency decisions. Under APA § 704, an agency cannot require an interested person to file an administrative appeal while the challenged decision remains in effect. *Idaho Watersheds*, 307 F.3d at 825. Under NEPA, post hoc "examination of data to support a pre-determined conclusion is not permissible." *Sierra Club v. Bosworth*, 510 F.3d 1016, 1026 (9th Cir. 2007). The purpose of NEPA is "to ensure that federal agencies take a 'hard look' at the environmental consequences of their actions, early enough so that it can serve as an important contribution to the decision making process." *Id.* (internal quotation omitted).

The district court ignored that Appellants' challenge is to multiple administrative processes that have *already* taken place, resulting in final decisions that represent both the consummation of FDA's thinking on the subject and decisions from which legal rights and obligations flow. *See Bennett*, 520 U.S. at 177-78 (An agency action is final for the purposes of judicial review if it (1) "mark[s] the 'consummation' of the agency's decision-making process," and (2)

"[is] one by which 'rights or obligations have been determined' or from which 'legal consequences flow.'") (citations omitted); 21 C.F.R. § 10.25 (an administrative proceeding may be initiated in one of three ways). The court's decision denies Appellants the right to challenge the validity of the animal drug approvals and creates a situation where FDA must reach a second, separate administrative decision before Appellants can seek relief. Appellants do not, however, need an additional final agency action to have a right to judicial review.

FDA is required to comply with NEPA in approving animal drugs. 21 C.F.R. § 25.1. Compliance with NEPA is not within FDA's discretion—it is mandatory for all federal agencies, *see Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 558-559 (9th Cir. 2000), and specifically required by FDA's own regulations, 21 C.F.R. pt. 25. FDA's NEPA regulations instruct the agency to assess environmental factors "at the earliest possible time to ensure that planning and decisions reflect the environmental values, to avoid delays later in the process, and to avoid potential conflicts." *Id.* § 25.10(b).

Appellants cannot be required to "exhaust administrative remedies" by filing a wholly separate citizen petition requesting the Agency to undertake the environmental analysis that it was legally required to conduct for each new animal drug approval. It is FDA, not Appellants, that has a statutory duty to comply with NEPA. *Dep't of Transp. v. Pub. Citizen* (*Public Citizen*), 541 U.S. 752, 764-65

(2004). "[F]ulfillment of this vital responsibility should not depend on the vigilance and limited resources of environmental plaintiffs" in pointing out FDA's flaws to it. *City of Davis v. Coleman*, 521 F.2d 661, 670-71 (9th Cir. 1975). This is especially true where, as here, Appellants lacked any opportunity to challenge the Agency's action during the review period. *See* 21 C.F.R. § 10.40(e)(3); *Ecology Ctr. of La., Inc. v. Coleman*, 515 F.2d 860, 865 (5th Cir. 1975); *Lands Council v. Vaught*, 198 F. Supp. 2d 1211, 1240-41 (E.D. Wash. 2002) (citing *Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522, 530 (7th Cir. 1993)).

Nor can Appellants be required to initiate a new administrative process while the underlying decisions Appellants are challenging remain effective. Elanco and others will continue to sell the animal drugs approved by FDA's deficient decisions, and facilities will continue to release those drugs into the environment. The Agency that failed to comply with NEPA in the first instance does not receive a second chance to do so, with a new administrative proceeding—especially while the underlying action continues to cause the environmental harms that NEPA was specifically designed to protect against. Only judicial review can give Appellants the remedies sought in this case: immediately vacating the approvals and removing the drugs from the market unless or until FDA corrects its failure and complies with NEPA. *See* ER033, 167, 196, 221. Therefore Appellants have a right to challenge FDA's failure to comply with NEPA in approving the animal drugs

without resort to further administrative processes. Depriving them of this right undermines the purposes of NEPA.

There is already a fully developed administrative record from FDA's eighteen final agency actions that is bereft of support for FDA's contention that it complied with NEPA.[7] *See* ER048-9; *cf. Am. Physicians*, 539 F. Supp. 2d. at 21-22 (finding that it would frustrate the purpose of exhaustion to allow judicial review of the decision without first allowing the agency to create a record). A citizen petition would create an entirely new record for the court to review, and would have no bearing on whether FDA complied with NEPA at the time it approved the eighteen ractopamine-based drugs at issue here. 21 C.F.R. § 10.30(j) (noting the administrative record for the purposes of a citizen petition is the exclusive record for FDA's decision). The district court can determine whether the Agency complied with its legal obligations under NEPA without any further record development. Therefore, a citizen petition would not serve the purposes of exhaustion here.

[7] FDA has not argued, nor can it, that there is no administrative record for the final agency actions Appellants challenge here. Indeed, FDA has produced several thousand pages that it considers the complete administrative record for this case. The district court's belief that FDA did not have a complete administrative record underlying the drug approvals, *see* ER008, is thus incorrect.

II. In the Alternative, the District Court Erred in Holding that it Did Not Have Discretion to Waive Exhaustion After Considering Appellants' Interests.

The district court wrongly concluded that "courts no longer have discretion to excuse failure to exhaust mandatory administrative remedies in APA cases." ER012 (citations omitted). This conclusion is predicated on the district court's fundamental misunderstanding of *Darby*, the APA, and the relief sought by Appellants. As explained above, courts do not have authority to require regulatory administrative procedures that do not comply with APA § 704. The FFDCA does not explicitly require exhaustion, and FDA's citizen petition regulations do not satisfy the requirements of APA § 704. For those reasons, compliance with the citizen petition provision is not a necessary predicate to a court's jurisdiction here. In the alternative, even if the Court believes FDA's citizen petition regulation is an exhaustion requirement, it is nonjurisdictional and the Court has discretion to—and should—waive it after considering Appellants' interests.

A. FDA's Citizen Petition Provision Is Nonjurisdictional.

Whether a court has discretion to waive an exhaustion requirement rests on the distinction between jurisdictional and nonjurisdictional exhaustion. *Munsell v. Dep't of Agric.*, 509 F.3d 572, 579 (D.C. Cir. 2007) ("The question here is whether Congress' enactment of 7 U.S.C. § 6912(e) imposes a *jurisdictional* or *nonjurisdictional* prerequisite to [plaintiffs'] actions and, in either event, whether

appellants satisfied the prescribed exhaustion requirements.") (emphases in original). "[A] mandatory [nonjurisdictional] exhaustion requirement may be excused in appropriate circumstances, whereas a jurisdictional exhaustion requirement never may be excused by a court." *Id.* (citing *Woodford v. Ngo*, 548 U.S. 81 (2006)). Thus, in cases where an exhaustion requirement is nonjurisdictional, the rules of administrative law contain "well-established exceptions" to such requirements. *Woodford*, 548 U.S. at 103 (Breyer, J., concurring in the judgment).

As explained above, unless exhaustion is explicitly required by the underlying statute—which is not the case here—APA § 704 grants agencies the authority to avoid a court's jurisdiction through regulations, but only under two conditions. *Darby*, 509 U.S. at 152. Agencies may preclude a decision from review under APA § 706 "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.* Unless both conditions of § 704 are met, APA § 704 does not act as an impediment to jurisdiction. *Id.*

Because FDA's citizen petition provision does not satisfy either of these elements—let alone both—it does not impede a court's jurisdiction to review otherwise final agency action, and is thus nonjurisdictional. *See Teva Pharm. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42, 51 (D.D.C. 2009), *rev'd on other grounds*,

595 F.3d 1303 (D.C. Cir. 2010) (treating 21 C.F.R. § 10.45 as nonjurisdictional); *Farm-to-Consumer Legal Defense Fund v. Sebelius*, 734 F. Supp. 2d 668, 699 (N.D. Iowa 2010) ("failure to exhaust administrative remedies is not a jurisdictional impediment" to suits challenging FDA action).

B. The Court Has Discretion to Waive Compliance with FDA's Citizen Petition Provision.

Because FDA's citizen petition regulation is nonjurisdictional, the Court has discretion to waive it.[8] *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30 (D.D.C. 1997) ("The Citizen Petition mechanism and its 180–day timeline is a creature of the FDA, not of Congress. Therefore, because Congress has not required exhaustion, 'sound judicial discretion governs' the question whether to require exhaustion of remedies.") (citing *McCarthy v. Madigan*, 503 U.S. 140, 144 (1992)); *Am. Physicians*, 539 F. Supp. 2d at 23-24. The district court ignored this rule of law and found that *Bracco Diagnostics* did not "endorse [Appellants'] view,

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[8] The district court's error is also apparent in the conflict between its holding that exhaustion was non-waivable—and thus necessarily jurisdictional—and its offer to stay the litigation while Appellants filed a citizen petition with FDA. But "it is not possible for this court to work within a jurisdictional vacuum . . . without the requisite jurisdiction, this court in these circumstances has no authority to grant a stay of proceedings." *Conn. Dep't of Children & Youth Servs. v. United States*, 16 Cl. Ct. 102, 105 (1989); *Lillis v. Nat'l Credit Onion Admin. Bd.*, No. 14-867, 2015 WL 134231, at *3 (D. Or. Jan. 9, 2015) (where "exhaustion of administrative remedies as a prerequisite to this Court's jurisdiction . . . this Court does not have jurisdiction to stay rather than dismiss Plaintiffs' claims.").

especially considering the decision does not address the implications of *Darby*." ER012. The court concluded that "the more reasonable interpretation is that the court [in *Bracco Diagnostics*] unfortunately overlooked *Darby*'s command that administrative remedies created by regulation and statute must be exhausted." ER012.

In dismissing *Bracco Diagnostics*, the court wholly ignored the sixteen post-*Darby* APA cases that Appellants presented, where the court stated it *could* waive exhaustion, even if, after utilizing its discretion, it declined to do so. *See* ER039-42. There are additional post-*Darby* APA cases that stand for this proposition that were not cited by any party below, including cases where the court did indeed waive exhaustion. *See Humane Soc'y of the U.S. v. Vilsack*, 797 F.3d 4, 7-8 (D.C. Cir. 2015) (excused failure to exhaust because administrative review would not offer adequate relief); *Idaho Watersheds*, 307 F.3d at 827; *Herr v. U.S. Forest Serv.*, 803 F.3d 809, 822 (6th Cir. 2015); *Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011); *Benoit v. USDA*, 608 F.3d 17, 22 (D.C. Cir. 2010); *Munsell*, 509 F.3d at 578-79; *Fox Television Stations, Inc. v. F.C.C.*, 280 F.3d 1027, 1040 (D.C. Cir. 2002), *opinion modified on reh'g*, 293 F.3d 537 (D.C. Cir. 2002); *W. Radio Servs. Co., Inc. v. Espy*, 79 F.3d 896, 899 (9th Cir. 1996) (refusing to require exhaustion of remedies at an agency that "does not have the authority to redress" a party's complaints.); *Wilczynski v. Lumbermens Mut. Cas.*

Co., 93 F.3d 397, 402 (7th Cir. 1996); *Pavano v. Shalala*, 95 F.3d 147, 150-52 (2d Cir. 1996); *Safari Club Int'l v. Jewell*, 76 F. Supp. 3d 198, 208 (D.D.C. 2014); *Lorillard, Inc. v. FDA*, No. 11-440, 2012 WL 3542228, at *3 (D.D.C. Aug. 1, 2012) (waiving exhaustion of FDA administrative remedies due to futility); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 24 (D.D.C. 2009) (exhaustion of remedies is futile and therefore excused because the agency may have had a policy contrary to law, and their expertise did not lend itself to resolution of the issues presented); *Montana Wilderness Ass'n v. Fr y*, 310 F. Supp. 2d 1127, 1139 (D. Mont. 2004) (excused failure to exhaust when the agency action would not be rendered inoperative); *see also Woodford*, 548 U.S. at 103 (Breyer, J., concurring in the judgment); *Teva Pharm. USA, Inc.*, 638 F. Supp. 2d at 51; *W. Watersheds Project v. U.S. Forest Serv.*, No. 07-151, 2007 WL 3407679, at *1 (D. Idaho Nov. 13, 2007). The court thus erred in concluding that courts no longer have discretion to waive nonjurisdictional exhaustion requirements.

C. The Court Abused Its Discretion in Declining to Waive Exhaustion Here.

In determining whether nonjurisdictional exhaustion provisions must be satisfied in a given case, "federal courts must balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." *McCarthy*, 503 U.S. at 146; *Porter v. Bd. of Trustees of Manhattan Beach Unified Sch. Dist.*, 307 F.3d 1064, 1071 (9th

Cir. 2002) (noting that the APA's exhaustion scheme was "carefully designed" to balance such interests). The Supreme Court has identified three broad sets of circumstances in which a plaintiff's interests weigh heavily against requiring judicial exhaustion: (1) when requiring exhaustion would cause "undue prejudice" as the result of an "unreasonable or indefinite timeframe for administrative action," (2) when there is "some doubt as to whether the agency was empowered to grant effective relief," or (3) when "the administrative body is shown to be biased or has otherwise predetermined the issue before it." *Id.* at 146-48 (internal citations and quotations omitted); *Am. Physicians*, 539 F. Supp. 2d at 23-24; *Teva Pharm USA*, 638 F. Supp. 2d at 51. A weighing of the Appellants' interests in this case counsels that exhaustion should be waived here.

1. Requiring a Citizen Petition Would Cause Undue Prejudice.

First, requiring exhaustion would cause "undue prejudice" as the result of an "unreasonable or indefinite timeframe for administrative action." *McCarthy*, 503 U.S. at 146. Predictable or even possible delay in completing the administrative appeals process can alone excuse a plaintiff's failure to exhaust administrative remedies before filing suit. *See id.* at 146 (citing cases where agency regulations lack a time limit to consider petitioners' claims or could allow a "possible delay of 10 years"). The Supreme Court has noted that courts "should be especially sensitive to [irreparable] harm where the Government seeks to require claimants to

exhaust administrative remedies merely to enable them to receive the procedure they should have been afforded in the first place." *Bowen v. City of New York*, 476 U.S. 467, 484 (1986).

That is precisely the case here. FDA's citizen petition regulations allow FDA to indefinitely delay a substantive response to a petition. *See* 21 C.F.R. § 10.30(e)(2). At least one court has recognized FDA's indefinite timeframe to respond to a citizen petition as sufficient to excuse plaintiffs from submitting one, because petitioning is unlikely "to secure immediate judicial consideration of [plaintiffs'] claim[s]." *Bracco Diagnostics*, 963 F. Supp. at 30 (quoting *McCarthy*, 530 U.S. at 147). Indeed, FDA is aware of its years-long—sometimes decades-long—delays in responding to citizen petitions.[9] Appellants have had to pursue litigation to compel FDA to respond to petitions, *see* Compl., *Ctr. for Food Safety v. FDA*, No. 13-01975 (N.D. Cal. Apr. 30, 2013), and such suits are not unusual, *see Ctr. for Sci. in the Pub. Interest v. FDA*, 74 F. Supp. 3d 295 (D.D.C. 2014) (litigation challenging FDA's three-year delay in acting on citizen petition);

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[9] *See generally* Office of the Inspector Gen., Dep't of Health & Human Servs., No. A-15-97-50002, *Review of the Food & Drug Administration's Citizen Petition Process* i (July 1998), https://oig.hhs.gov/oas/reports/phs/c9750002.pdf ("The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's.").

Nat. Resources Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 137 n.6 (S.D.N.Y. 2012), *rev'd*, 760 F.3d 151 (2d Cir. 2014) (litigation challenging FDA's six- and twelve-year delays in responding to citizen petitions); *Pub. Citizen v. Heckler*, 602 F. Supp. 611, 612-14 (D.D.C. 1985) (holding that FDA unreasonably delayed responding to citizen petition).

While waiting (indefinitely) for a response, Appellants will continue to suffer irreparable harm from the impacts of ractopamine and ractopamine-based animal drugs on human health and the environment, ER081, 174-82, 205-9, because the citizen petition process does not render the drug approvals inoperative while FDA considers the petition, *supra* § I.A. This harm is the direct result of FDA's failure to comply with NEPA's mandate to conduct adequate NEPA analyses *before* approving the animal drugs. Appellants should not be required to withstand harm while FDA continues to ignore this failure.

Despite this, the district court mistakenly found that Appellants were required to show that FDA would delay in responding to their not-yet-submitted petition, ER013, with no regard to the case law's allowance for the court to consider whether the administrative procedure at issue creates the possibility or likelihood of delay, *see McCarthy*, 503 U.S. at 146-147 (citing *Walker v. Southern Ry. Co.*, 385 U.S. 196, 198 (1966) (possible delay of ten years in administrative proceedings makes exhaustion unnecessary). The district court also did "not find

[Appellants'] claims of injustice compelling given that they waited until November 2014 to file these lawsuits challenging FDA approvals issued beginning in 2008." ER013. This ignores the fact that Appellants did not become aware of the deficiencies in the approvals until after FDA released documents under FOIA in April 2014—and only after Appellants sued FDA to do so, *see* ER047—and that the time range of approvals challenged in the litigation ran until just two months before Appellants filed suit, *see* ER191-2, 216-7.

2. FDA Cannot Grant Appellants the Relief They Seek.

Second, there are serious "doubt[s] as to whether the agency [i]s empowered to grant effective relief." *McCarthy*, 503 U.S. at 147 (quoting *Gibson v. Berryhill*, 411 U.S. 564, 575 n.14 (1973)). FDA's citizen petition process and the remedies contemplated by the FFDCA and its implementing regulations are genuinely distinct from the remedies Appellants seek in this case under NEPA. Once FDA approves a drug, the FFDCA provides specific sets of circumstances in which FDA can withdraw approval when concerning a drug's safety. 21 U.S.C. § 360b(e)(1). Each is based on new evidence generated after the drug approval, and only in the context of human and animal health. *Id.* In considering withdrawal, the FFDCA is silent on harms to plant species, water quality, wildlife habitat, or other indirect effects that Appellants raise in their Complaints. *Id.*; *id.* § 321(u) ("The term 'safe' . . . has reference to the health of man or animal."); Phibro Animal Health Corp.;

Carbadox in Medicated Swine Feed; Opportunity for Hearing, 81 Fed. Reg. 21,559, 21,562 (Apr. 12, 2016) (explaining that in determining the "safety" of an animal drug for the purposes of withdrawing the drug, "the Agency is required . . . to consider . . . [t]he cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, i.e., toxicological effects of the compounds comprising the residues."). Thus, once FDA has taken final action in approving an animal drug, it lacks the legal authority under the FFDCA to suspend or withdraw the approval based solely on a prior failure to adequately analyze the environmental impacts of the drug.

Accordingly, Appellants requested declaratory and injunctive relief pursuant to NEPA, in the form of vacatur of the initial approvals—not drug withdrawal pursuant to the FFDCA. *See* ER033, 167, 196, 221 ("Under Defendants' reading of the remedies sought in the complaints, Plaintiffs in these case[s], like in [*Merrell v. Thomas*], seek to compel FDA to comply with NEPA, rather than, as Elanco suggests, to withdraw or suspend the animal drug approvals under the Federal Food, Drug, and Cosmetic Act ('FDCA'), 21 U.S.C. § 360b(e)(1).").

The citizen petition process cannot provide Appellants with this relief. *See W. Radio Servs. Co., Inc.*, 79 F.3d at 899 (refusing to require exhaustion of remedies at an agency that "does not have the authority to redress" a party's complaints); *Humane Soc'y of the U.S.*, 797 F.3d at 7-8 (holding plaintiffs were not

required to pursue administrative remedies because "[t]he statute's provision for administrative review would not offer the plaintiffs adequate relief"); *Fox Television Stations, Inc.*, 280 F.3d at 1040 (exhaustion waived where it would be futile and the relief available from the agency was not the relief petitioners sought in their lawsuit). Were Appellants to submit a citizen petition pursuant to the FFDCA asking FDA to suspend or withdraw approval for ractopamine-based drugs solely on the basis that the Agency did not comply with NEPA in approving the drugs, the only relief FDA could provide is a *post hoc* environmental review of the existing drug approvals while the drugs remain on the market, continue to contaminate the environment, and irreparably harm Appellants. The only challengeable decision to arise from the process would be a separate final action either granting impermissible *post hoc* NEPA review, or denying the petition. This is antithetical to NEPA and the APA, and not the relief that Appellants seek.

Further, even if FDA could initiate FFDCA withdrawal proceedings for ractopamine in response to a citizen petition here—which, again, Appellants are not requesting—beginning the withdrawal process cannot be characterized as the relief Appellants request under NEPA. Rather, it is a complicated procedure that takes years, if not decades, to carry out; it is not guaranteed to result in drug withdrawal; and it still does not guarantee an opportunity for Appellants to raise their concerns to the Agency. *See* 81 Fed. Reg. at 21,559-60 (announcing

opportunity to request hearing on animal drug withdrawal and explaining that information marked as "confidential" will not be disclosed except in accordance with 21 C.F.R. § 10.20 and other applicable disclosure laws). FDA will not necessarily consider ractopamine's environmental effects during withdrawal proceedings, and the drugs could remain on the market, indefinitely, until FDA's final decision to withdraw them at the conclusion of this process. This is nothing like the immediate and straightforward injunctive and declaratory relief Appellants requested and are entitled to. *See High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 640 (9th Cir. 2004) ("[W]hen an agency has taken action without observance of the procedure required by law, that action will be set aside."); *Anderson v. Evans*, 371 F.3d 475, 494 (9th Cir. 2002) (vacating approvals "[b]ecause the agencies have not complied with NEPA").

Nevertheless, the district court mischaracterized the declaratory and injunctive relief requested in Appellants' Complaints and conflated it with the entirely separate process of withdrawing drug approval under the FFDCA. The court mistakenly concluded that "[i]n response [to a citizen petition], the [A]gency may withdraw/vacate the FDA approvals—the remedy sought by [Appellants]—should it conclude that new evidence or changed circumstances require new NEPA review." ER014 (citing 21 U.S.C. § 360b(e)(1), which authorizes drug withdrawal on the basis of threats to animal or human health). In doing so, the court

independently revised Appellants' claims, and then rejected them based on a misunderstanding of the statutory scheme. In fact, neither Complaint requests withdrawal of the drugs, nor even cites to the FFDCA withdrawal provisions on which the district court relied. In light of the limitations on FDA's ability to grant effective NEPA relief through the FFDCA's citizen petition process, the court should not have required Appellants to carry out that process here.

3. FDA Has Predetermined the Issue Before It.

Finally, FDA is "biased or has otherwise predetermined the issue before it." *McCarthy*, 503 U.S. at 148 (citing *Gibson*, 411 U.S. at 575 n.14). Bias or a predetermined outcome renders exhaustion futile, which excuses plaintiffs from exhaustion. *See id.* at 149; *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 564 (9th Cir. 1992) (exhaustion not required "where pursuit of administrative remedies would be a futile gesture" (internal quotations omitted)); *Athlone Indus., Inc. v. Consumer Prod. Safety Comm'n*, 707 F.2d 1485, 1489 (D.C. Cir. 1983) (when exhaustion likely futile, "the cause of overall efficiency will not be served by postponing judicial review, and the exhaustion requirement need not be applied"); *Herr*, 803 F.3d at 822. FDA openly 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*." ER061

(emphasis added). FDA apparently applies this policy to all animal drug applications, regardless of whether FDA is actually aware that an action should not be categorically excluded from NEPA analysis. It has predetermined that no additional NEPA analysis is necessary beyond what the drug sponsors have already done, regardless of what circumstances or information a petitioner may present to the contrary. Thus a request that the Agency conduct a proper or further NEPA analysis would be futile.

Here the district court found that, without reviewing the administrative record, the evidence presented of FDA's predetermination did not sufficiently demonstrate FDA's "final position"—a rule that is not derived from the case law on predetermination—and did not convince the court that FDA would actually apply that predetermination in response to a citizen petition. ER014. Accordingly, even though the court found the information "troubling," it "remain[ed] convinced that the prudent course *requires* it to allow the FDA its opportunity to resolve [Appellants'] grievances administratively." ER014 (emphasis added). This again demonstrates the court's misunderstanding of the applicable law, the existence of a record, and its discretion to excuse exhaustion in this case. *Korab*, 797 F.3d at 577 (A district court necessarily abuses its discretion if it bases its ruling based on an erroneous view of the law); *In re Arden*, 176 F.3d at 1228 (an exercise of

discretion based on an erroneous interpretation of the law can be freely overturned).

Further, in so deciding, the court erred by relying on materials outside the scope of the Complaints without converting the motion into a motion for summary judgment. ER014 (citing to, but ultimately rejecting, one document from the administrative record). "When the district court looks outside the pleadings in evaluating a noticed Rule 12(b)(6) motion, the motion must be converted and treated as one for summary judgment under Rule 56." *Portland Retail Druggists Ass'n v. Kaiser Found. Health Plan*, 662 F.2d 641, 645 (9th Cir. 1981) (internal citations omitted). While Appellants introduced this document into the record, the court's decision to rely on it without converting the motion served to deny Appellants "sufficient opportunity to discover and bring forward factual matters which may become relevant only in the summary judgment, and not the dismissal, context." *Id.* The court's reliance on extra-complaint materials without considering the full administrative record prejudiced Appellants and constitutes a further error of law.

4. A Citizen Petition Does Not Serve the Purpose of Exhaustion.

The district court also failed to weigh all of these interests in light of whether exhaustion in this case would further the government's interests in efficiency or administrative autonomy, which the exhaustion doctrine is designed

to protect. *See McCarthy*, 503 U.S. at 146. As explained above, requiring Appellants to start and complete an entirely new, and indefinitely lengthy, administrative proceeding before challenging a final agency action that is already reviewable under the APA runs directly counter to efficiency and to the purposes of the exhaustion doctrine and NEPA.

The district court and Appellees made much of the fact that FDA did not have an opportunity to consider the information that Appellants would present in a citizen petition. This is not the case. Appellants' Complaints are based on environmental information that was already in front of the Agency—or the lack thereof, which should have been so obvious that Appellants need not be required to point it out—at the time of the relevant ultimate approvals. *See*, *e.g.*, ER188-90 (stating the analysis relied upon in FDA's NEPA documents was between four and fifteen years old at the time of the approvals); ER213 (same); *Barnes v. U.S. Dep't of Transp.*, 655 F.3d 1124, 1133 (9th Cir. 2011) (noting that a NEPA document's "flaws 'might be so obvious that there is no need for a commentator to point them out specifically in order to preserve its ability to challenge a proposed action.'") (internal quotation omitted); *Hall*, 689 F. Supp. 2d at 24 (exhaustion of administrative remedies excused in part because agency expertise did not lend itself to resolution of the issues presented). FDA was likewise aware of the superficial nature of its NEPA compliance and its reliance on outdated statistics in

reaching its final decision to approve ractopamine-based drugs, *see, e.g.*, ER189-90, 213, so it "cannot reasonably claim that it has been denied the opportunity to consider the issue," *Am. Forest & Paper Ass'n v. EPA*, 137 F.3d 291, 295-96 (5th Cir. 1998) (citing *Unemployment Comp. Comm'n v. Aragon*, 329 U.S. 143, 155 (1946)); *see also Barnes*, 655 F.3d at 1134-1135 (refusing to require exhaustion where "the agencies had independent knowledge" of the issue (quoting *Pub. Citizen*, 541 U.S. at 765)); *Ilio'ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1093 (9th Cir. 2006) (finding that plaintiffs did not waive their right to challenge the sufficiency of an agency's decision because the agency "had independent knowledge of the very issue that concerns [p]laintiffs in this case.").

Thus, even assuming that Appellants were required to comply with FFDCA's citizen petition provision, the district court had discretion to waive compliance with that provision because Appellants would be unduly prejudiced by an indefinite response period, the Agency has predetermined the issue before it, the citizen petition process would not grant Appellants the relief they seek, and it would not serve the purposes of efficiency in this case. The court abused its discretion by declining to waive compliance here.

CONCLUSION

The district court's decision would insulate FDA's animal drug approvals from judicial review. Because FDA's ractopamine approvals are final agency

actions, and FDA's citizen petition regulations are not exhaustion provisions under APA § 704, Appellants respectfully request this Court set aside the district court's decision and remand this matter to the district court for consideration of Appellants' claims.

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Respectfully submitted,

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STATEMENT OF RELATED CASES

Appellants are not aware of any related case pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points or more and contains 11,648 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

Dated: May 10, 2016.

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