United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, *et al.*,

Plaintiffs,

and

HUMANE SOCIETY OF THE UNITED STATES, *et al.*,

Plaintiffs,

v.

MARGARET A. HAMBURG, Commissioner, United States Food and Drug Administration, *et al.*,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Consolidated Case Nos. 14-cv-04932-YGR and 14-cv-04933-YGR

ORDER ON INTERVENOR-DEFENDANT'S MOTION TO DISMISS; ORDER TO SHOW CAUSE RE: STAY PENDING EXHAUSTION

Re: Dkt. No. 58

Plaintiffs Center for Food Safety, *et al.*, (collectively, "plaintiffs") bring these cases against defendants United States Food and Drug Administration ("FDA") and Margaret Hamburg, in her official capacity as the Commissioner of the FDA (collectively, "defendants"), alleging violations of the National Environmental Protection Act ("NEPA") and the Administrative Procedure Act ("APA"). Plaintiffs seek declaratory and injunctive relief directing the FDA to comply with NEPA and its implementing regulations with respect to approval of ractopamine hydrochloride ("ractopamine") and ractopamine combination animal drugs from 2008 to 2014. On March 5,

2015, the Court consolidated the two cases for all purposes. (Dkt. No. 32.)[1] Intervenor-defendant Elanco Animal Health ("Elanco") moved to intervene in both cases, and on April 1, 2015, the Court granted Elanco's motion. (Dkt. No. 45.)

Pending before the Court is defendant-intervenor Elanco's[2] motion to dismiss the complaints for plaintiffs' failure to exhaust administrative remedies. (Dkt. No. 58, "Mtn.") Having carefully considered the papers submitted[3] and the pleadings in this action, oral argument on September 8, 2015, and for the reasons set forth below, the Court hereby **GRANTS** Elanco's motion to dismiss the complaints.

I. BACKGROUND

The FDA first approved the use of ractopamine in 1999 for pigs and later approved it for cattle and turkeys. (Dkt. No. 1, "CFS Compl.," ¶ 36; Dkt. No. 1, 14-cv-4933, "HSUS Compl.," ¶ 34.) Ractopamine has a number of metabolic effects on animals, including a shift in dietary energy balance "toward skeletal muscle growth as opposed to fat deposition." (CFS Compl. ¶ 31; HSUS Compl. ¶ 27.) Elanco manufactures ractopamine, and markets the drug as a "feed additive to induce faster growth and leaner meat in pigs, cattle, and turkeys." (CFS Compl. ¶ 35; HSUS Compl. ¶ 27.) Ractopamine is also used in combination with other pharmaceuticals, including tylosin, monensin, and melengestrol. (CFS Compl. ¶¶ 68-99; HSUS Compl. ¶¶ 73-103.)

Plaintiffs are public interest organizations whose missions include protecting human health and the environment by, for example, "challenging harmful food production technologies and promoting sustainable alternatives." (CFS Compl. at ¶ 11.) Additionally, the missions of certain

[1] Except where explicitly stated otherwise, and pursuant to the Court's order consolidating the cases, all references to the docket are to the main docket, Case No. 14-cv-4932-YGR.

[2] Defendants originally did not join in Elanco's motion to dismiss. At the hearing on September 8, 2015, counsel for defendants represented that they believed that some, but not all, of plaintiffs' claims were subject to dismissal for failure to exhaust. (*See* Dkt. No. 76 at 9-10.) Defendants later changed their position, now arguing that Elanco's motion should be granted and plaintiffs' claims dismissed entirely.

[3] Following the September 8, 2015 hearing, the parties submitted a series of supplemental briefs in support of their arguments on application of the administrative exhaustion requirement. (*See* Dkt. Nos. 73-75, 80, 84, 87.)

plaintiffs focus on animal protection and animal health risks (HSUS Compl. at ¶¶ 8, 17), as well as the interests of farmworkers in the United States (*Id*. at ¶ 11). Plaintiffs bring this consolidated action to challenge the FDA's approval of animal drug applications for animal drugs containing ractopamine. (CFS Compl. ¶ 1; HSUS Compl. ¶ 1.) Specifically, plaintiffs allege that that FDA did not comply with the requirements of NEPA[4] with respect to its consideration of impact on the environment when it approved the ractopamine-containing animal drug applications beginning in 2008 (the "FDA approvals"). (CFS Compl. ¶ 120; HSUS Compl. ¶ 119). Plaintiffs allege that, as a result of FDA's inadequate NEPA review, the FDA approvals were "arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with NEPA…and must be set aside." (CFS Compl. ¶ 138, 149; HSUS Compl. ¶ 131, 135.) Plaintiffs therefore request, primarily, that the Court: (i) declare that the FDA approvals violated NEPA and its implementing regulations; and (ii) vacate and remand the FDA approvals to FDA. (*See* CFS Compl.; HSUS Compl.) Moreover, the CFS complaint requests that the Court issue a preliminary and permanent injunction "barring the use of ractopamine-based animal drugs until FDA complies with NEPA." (CFS Compl., Prayer for Relief, ¶ 3.)

Due to statutory and regulatory requirements that applications to FDA for new drugs remain confidential, *see* 21 U.S.C. § 331(j); 21 CFR §§ 514.11, 514.12, plaintiffs only became aware of the approvals, and FDA's associated decision-making, when they were final and published in the Federal Register. (CFS Compl. ¶ 118, 121; HSUS Compl. ¶ 117, 122.) Thus, plaintiffs were not able to participate in the administrative process prior to the FDA approvals at issue. (*Id*.) Central to defendant-intervenor's motion to dismiss, plaintiffs do not allege that they pursued any administrative remedies with the FDA relating to their NEPA grievances following the FDA approvals. As discussed more fully below, plaintiffs actually concede the same but contend that either they were not required to do so, or in the alternative, that the Court should

[4] The CFS complaint also generally alleges that the FDA's approvals were "without observance of procedures required by the APA," but fails to state the manner in which these violations occurred. (CFS Compl. ¶¶ 138, 149). The APA is the statutory mechanism by which plaintiffs seek this Court's review of the FDA's action, and plaintiffs do not separately assert in any sufficient detail that the FDA violated the APA when it approved the drugs at issue.

waive the exhaustion requirement under these circumstances.

II. DISCUSSION

A. Statutory Framework

Congress enacted NEPA in 1969 to protect the environment by requiring federal agencies to follow certain procedural steps before taking any action affecting the environment. On its own, NEPA "does not provide a private cause of action for violation of its provisions." *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1353 n. 13 (9th Cir. 1994). Thus, plaintiffs correctly proceed under the APA, which does provide a cause of action to parties seeking judicial review of agency NEPA decisions, subject to several limitations. *See id.*; 5 U.S.C. § 702.

Relevant here is the APA's requirement "that plaintiffs exhaust available administrative remedies before bringing their grievances in federal court." *Idaho Sporting Congress, Inc. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir. 2002) (citing 5 U.S.C. § 704). "The purpose of the exhaustion doctrine is 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 v. Secretary of U.S. Dept. of Agr.*, 603 F.3d 1073, 1080 (9th Cir. 2010) (quoting *United Farm Workers v. Ariz. Agric. Employment Relations Bd.*, 669 F.2d 1249, 1253 (9th Cir. 1982)). The APA requirement that plaintiffs exhaust administrative remedies "applies to claims under NEPA." *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 965 (9th Cir. 2006); *See Save Strawberry Canyon v. U.S. Dept. of Energy*, 830 F.Supp.2d 737, 745 (N.D.Cal. 2011) ("[a] NEPA plaintiff must exhaust administrative remedies before seeking judicial review of the administrative process").

The APA does not mandate a particular process by which a plaintiff must exhaust administrative remedies before seeking judicial review in federal court. Rather, the exhaustion doctrine exists under the APA only "to the extent that it is required by statute or agency rule as a prerequisite to judicial review." *Darby v. Cisnero*, 509 U.S. 137, 153 (1993). Although the FDA approval process is relatively closed to the public, the FDA has created a regulatory mechanism by which interested persons may challenge the Commissioner's activities under the Food, Drug, and

Cosmetic Act ("FDCA"). *See* 21 CFR §§ 10.1(a), 10.25(a), 10.45(b). Namely, 21 CFR section 10.25(a) provides, in pertinent part: "[a]n interested person may petition the Commissioner to issue, amend or revoke a regulation or order, or to take or refrain from taking any other form of administrative action….in the form of a citizen petition." *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 2009 WL 8727693, at *2 (C.D.Cal. Feb. 17, 2009) ("Any person may try to affect FDA action…The FDA encourages this, maintaining an open invitation to the public to file a 'citizen petition.'"). Not only do the FDA regulations allow an interested person to file a citizen petition, but they also mandate that any "request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a)…before any legal action is filed in a court complaining of the action or failure to act." 21 CFR 10.45(b).

The FDA regulations, therefore, "*require* that a request" be made to the Commissioner before filing a complaint in court complaining of an administrative action or failure to act. *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F.Supp.2d 4, 21 (D.D.C. 2008) (emphasis in original). Failure to comply with this exhaustion requirement warrants dismissal of a grievance filed in federal court in the first instance. *See id., affirmed by* 358 F.App'x 179, 180-81 (D.C. Cir. 2009) (appellants failed to exhaust their administrative remedies where they "filed no such citizen petition with the FDA"); *Dietary Supplement Coalition, Inc. v. Sullivan*, 796 F.Supp. 441, 446 (D.Or. 1991) (dismissing complaint, in part, because plaintiff failed to exhaust administrative remedies by filing a citizen petition with the FDA); *IMS Ltd. v. Califano*, 453 F.Supp. 157, 160 (C.D.Cal. 1977) (noting that plaintiffs could have, but chose not to, file a citizen petition as an avenue to exhaust administrative remedies with the FDA). The citizen petition requirement applies to all "administrative proceedings and activities conducted by the [FDA] under the [FDCA] … and other laws that the Commissioner of Food and Drugs *administers*." 21 CFR § 10.1 (emphasis supplied).

B. Analysis

Plaintiffs do not contest that the above-cited FDA regulations generally require an interested person to file a citizen petition before filing a complaint in federal court compelling the

FDA Commissioner to take administrative action. Instead, plaintiffs present three arguments why failure to exhaust does not defeat their claims, namely: (1) the FDA's exhaustion requirement found in 21 CFR section 10.45(b) does not apply here because plaintiffs bring claims under NEPA, not the FDCA; (2) should the Court find the exhaustion requirement applicable here, plaintiffs implore the Court to invoke certain statutory and judicially-created exceptions to excuse or waive their failure to exhaust; and (3) regardless, defendants waived their right to raise the exhaustion argument and Elanco does not have standing to pursue it in their stead. The Court addresses these arguments in turn.

1. The FDA Exhaustion Requirement Applies To Plaintiffs' Grievances

Plaintiffs first contend that because NEPA and the FDCA are "two entirely distinct statutory mechanisms," the FDA's exhaustion requirement is inapplicable to their claims. (Dkt. No. 60, "Oppo.," at 3:6.) In support of this argument, plaintiffs state that the remedies they seek under NEPA and the APA are "*fundamentally different*" than the relief that FDA's citizen petition process could provide them. (Oppo. at 4:9-10) (emphasis in original). Even a cursory review of the complaints shows otherwise.

A NEPA review "cannot be entirely divorced from some underlying substantive federal decision," in this case, to issue the FDA approvals. *Portland Audubon Soc. v. Lujuan*, 884 F.2d 1233, 1239 (9th Cir. 1989) (although NEPA claim was not phrased as a direct challenge to the underlying federal action, the NEPA claim was nonetheless barred by statutory prohibition against challenges to the underlying federal action). Plaintiffs essentially argue that NEPA challenges are somehow specially exempt from the APA's clear command requiring administrative exhaustion because, in their view, only "[t]he [Counsel on Environmental Quality ("CEQ")] administers NEPA." (Oppo. at 6:17.) *Cf. Darby*, 509 U.S. at 147 (the APA "explicitly requires exhaustion of all intra-agency appeals mandated either by statute or by agency rule …"). However, NEPA does not contain its own right of action.

A "NEPA plaintiff must exhaust administrative remedies before seeking judicial review of the administrative process." *Save Strawberry Canyon*, 830 F.Supp.2d at 745; *see Great Basin Mine Watch*, 456 F.3d at 965. Intra-agency administrative exhaustion of NEPA grievances is

indisputably required regardless of whether a plaintiff's claims relate to actions taken by the FDA or any other federal agency. *See Great Basin Mine Watch*, 456 F.3d at 965 (evaluating exhaustion of administrative remedies through agency-specific procedure in connection with a NEPA challenge against the U.S. Department of the Interior); *Pacific Coast Federation of Fishermen's Associations v. U.S. Dept. of the Interior*, 996 F.Supp.2d 887 (E.D.Cal. 2014) (same); *AquAlliance v. U.S. Bureau of Reclamation*, 2014 WL 3401390 (E.D.Cal. July 11, 2014) (same, with respect to the U.S. Bureau of Reclamation); *Strawberry Canyon*, 830 F.Supp.2d at 745 (same, with respect to the U.S. Department of Energy); *Winnemem Wintu Tribe v. U.S. Dept. of Interior*, 725 F.Supp.2d 1119, 1139 (E.D.Cal. 2010) (same, with respect to U.S. Department of Interior); *The Lands Council v. Vaught*, 198 F.Supp.2d 1211, 1240-41 (E.D.Wash. 2002) (same, with respect to U.S. Forest Service).

The Ninth Circuit has rejected a similar attempt by a plaintiff to evade dismissal by framing claims as NEPA-only challenges proceeding exclusively pursuant to NEPA and the APA. *Turtle Island Restoration Network v. U.S. Dept. of Commerce*, 438 F.3d 937 (9th Cir. 2006). In *Turtle Island*, a NEPA plaintiff argued that their NEPA claims should be subject to the APA's six year statute of limitation rather than a narrow jurisdictional statute limiting the window for judicial review of such agency regulations. There, the complaint revealed that the NEPA claims were "directed at the regulations," and that plaintiff could not include NEPA language as a "stand alone challenge to agency action, distinct from the issuance of regulations," purely to take advantage of the APA's more generous catch-all statute of limitation. *Id*. at 945. Likewise, plaintiffs here cannot frame their challenges as under NEPA and the APA to evade their obligation to exhaust administrative remedies under the FDCA. Allowing plaintiffs to ignore the specific exhaustion requirement under the FDCA because they proceed under the APA would make "little sense," as in *Turtle Island*. *Id*. The APA plainly incorporates intra-agency exhaustion requirements, and plaintiffs cannot suggest otherwise.

Plaintiffs pointed to *Merrell v. Thomas*, 807 F.2d 776, 782 n. 3 (9th Cir. 1986), for the first time at the hearing, for the proposition that exhaustion under an agency's rules is not required as a prerequisite to judicial review of a NEPA challenge. In *Merrell*, plaintiffs sought to enjoin the

Environmental Protection Agency ("EPA") from registering herbicides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") without first complying with NEPA. The Ninth Circuit ultimately held that EPA was never obligated to comply with NEPA when it registered pesticides under FIFRA. *Id*. at 781. Specifically, plaintiffs here rely on a footnote in which the Ninth Circuit noted it reached the merits because it did "not hold that [plaintiff's] conduct amounted to a failure to exhaust administrative remedies" as required under the APA. *Id*. at 782, n.3. As an initial matter, *Merrell* was decided before the Supreme Court made clear in *Darby* that exhaustion, "to the extent that it is required by statute or agency rule as a prerequisite to judicial review," under section 702 of the APA. *Darby*, 509 U.S. at 153. Moreover, *Merrell* involved a purely legal question, *i.e.*, whether the EPA must engage in a NEPA analysis when registering a pesticide under FIFRA. The issue here is whether the FDA properly engaged in the NEPA analysis, which requires inquiry into the facts developed in the administrative record – a record the FDA has not fully developed in the absence of plaintiffs' participation in a citizen petition process. The question is not whether the FDA should be forced to engage in NEPA analyses with respect to drug approvals in the future. Rather, it is whether the FDA's NEPA analysis was deficient in particular instances, and if so, whether the FDA approvals should be withdrawn or vacated. *See Merrell*, 807 F.2d, 782 n.3 ("[i]f [plaintiff] had sued to cancel or suspend pesticide registrations, [a holding that plaintiff failed to exhaust] might be appropriate"). For all of these reasons, the Court finds that *Merrell* does not control.

Plaintiffs further contend that the FDA regulatory scheme containing the citizen petition requirement is inapplicable because it only applies to actions of the Commissioner undertaken with respect to statutes the FDA "administers." 21 CFR § 10.1. In that regard, plaintiffs contend that the FDA does not administer NEPA (or the APA) and so the claims in their complaints do not fall within the citizen petition requirement in 21 CFR section 10.45(b). In plaintiffs' view, FDA (like all federal agencies) merely complies with NEPA, and does not administer it under the meaning of the rule. While plaintiff's premise – that all federal agencies are entrusted to comply with NEPA – is correct, it does not follow that federal agencies are not also administering NEPA in order to achieve compliance. *See Grand Canyon Trust v. Federal Aviation Admin.*, 290 F.3d

339, 341 (D.C. Cir. 2002) ("NEPA is addressed to all federal agencies and Congress did not entrust administration of NEPA to [one federal agency] *alone*") (emphasis supplied). Indeed, plaintiffs ask this Court to order the FDA to comply with the statutory structure set forth in NEPA, necessarily requiring FDA to administer NEPA in some measure.

Plaintiffs draw an analogy between the FDA's obligations under NEPA and its obligations under the Freedom of Information Act ("FOIA"), to the extent that the FDA must comply with, but does not exclusively administer, both NEPA and FOIA. Because FDA does not require the citizen petition process be followed for FOIA grievances against FDA, plaintiffs claim it should similarly not apply to NEPA claims. But plaintiffs overlook an important difference between FOIA and NEPA. Namely, FOIA contains its own private right of action and prescribes its own administrative procedures for administrative review and judicial remedies. 5 U.S.C. § 552(a). NEPA, by contrast, does not. As discussed above, a plaintiff's exclusive right to judicial review of an agency's NEPA procedures is under the APA, and only if a plaintiff has satisfied the agency's statutory or regulatory exhaustion requirements. 5 U.S.C. §§ 702, 704. Thus, plaintiffs' FOIA analogy is flawed.[5]

Accordingly, the Court concludes that plaintiffs' NEPA challenges are subject to the regulatory requirement that a citizen petition be filed with the FDA, and the FDA must respond thereto, before plaintiffs are entitled to file to a claim in federal court.

2. No Exceptions To The Exhaustion Requirement Apply Here

In the alternative, plaintiffs contend that the Court should excuse compliance with any applicable exhaustion requirement. The Court addresses plaintiffs' arguments in turn below.

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[5] Plaintiffs' reliance on cases involving the Endangered Species Act ("ESA") for the proposition that the FDA's citizen petition process does not apply is similarly flawed. *See, e.g., Coal. for a Sustainable Delta v. FEMA*, 812 F.Supp.2d 1089, 1130 (E.D.Cal. 2011) ("[National Flood Insurance Act's (NFIA)] administrative review procedures reveal no legislative intent to require exhaustion of the NFIA's procedures prior to an ESA challenge"). As the court recognized in *Coalition for a Sustainable Delta*, the ESA, unlike NEPA, authorizes its own private right of action and does not itself require exhaustion. *Id*. at 1105, 1129. Thus, judicial review of compliance with the ESA does not implicate the APA's mandate that plaintiffs first exhaust administrative remedies provided by statute and regulation.

a. The "Inoperative" Exception in 5 U.S.C. § 704 Does Not Apply

First, plaintiffs argue that the FDA's exhaustion requirement should not apply because a citizen petition would not render the challenged FDA approvals "inoperative." Plaintiffs rely on language in APA's section 704, and the Supreme Court's interpretive statements in *Darby*, 509 U.S. at 154, in support of their argument that exhaustion is not required where the administrative process would not render the FDA approvals "inoperative." Section 704 provides in pertinent part:

> …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.

As Elanco properly states in reply, *Darby* does not validate plaintiffs' position. The Supreme Court made clear in *Darby* that the "inoperative" exception applies only to *optional* administrative remedies, and section 704 otherwise requires exhaustion of administrative remedies that a "statute or rule clearly mandates." *Darby*, 509 U.S. at 146; *see Acura of Bellevue v. Reich*, 90 F.3d 1403, 1408 (9th Cir. 1996) ("*Darby* held that a person aggrieved by an agency decision is not required to exhaust *nonmandatory* administrative remedies…before seeking judicial review") (emphasis supplied). Because FDA's citizen petition requirement is mandatory, the "inoperative" exception in section 704 is inapplicable.[6] *See* 21 CFR 10.45(b).

b. Plaintiffs Have a Meaningful Opportunity to Participate

Next, plaintiffs contend that they should not be required to exhaust because they have not been provided a meaningful opportunity to participate in the administrative process. Plaintiffs principally rely on a decision from the District of Colorado for this proposition. *See Dine Citizens Against Ruining Our Env't v. Klein*, 676 F.Supp.2d 1198, 1211 (D. Colo. 2009). In *Dine Citizens*, the court concluded that the plaintiffs' NEPA claims were not subject to dismissal on a Rule

[6] The Court also notes that the limitations in section 704 could not excuse plaintiffs' failure to exhaust because the citizen petition is not an "appeal to superior agency authority." 5 U.S.C. § 704. It is undisputed that plaintiffs have never raised their NEPA claims to any FDA authority. Because section 704 is inapplicable, the Court need not reach whether plaintiffs have an appropriate mechanism to render the FDA approvals "inoperable" pending the citizen petition.

12(b)(6) motion despite their failure to exhaust these claims before filing suit based on plaintiffs' allegations in their complaint that the agency had "an ongoing pattern and practice of violating NEPA and NEPA's implementing regulations by failing to provide adequate notice to the public of [the agency]'s NEPA process…and by failing to provide a meaningful opportunity for the public to participate in this process." *Id*. If proved, the court reasoned that these allegations "would excuse [p]laintiffs' failure to challenge [the agency's] NEPA compliance before the agency prior to bringing this action." *Id*. Plaintiffs' reliance on *Dine Citizens* is misplaced. There, the court initially held that the Department of the Interior, Office of Surface Mining Reclamation and Enforcement's implementing statute and regulations did not contain any mandatory exhaustion requirements such that the APA would require exhaustion. *Id*. at 1208-09. By contrast, here, the FDA's regulations mandate interested persons, such as plaintiffs, to file a citizen petition before filing a court action. 21 CFR 10.45(b).

Moreover, plaintiffs' premise that they have not been provided a meaningful opportunity to participate in the administrative process is not sound. The FDA citizen petition regulations provide plaintiffs with the opportunity to raise their NEPA concerns with the agency. The Court is unconvinced by plaintiffs' claim that "NEPA does not demand such participation." (Oppo. at 16:7-8.) Again, whether NEPA contains a separate exhaustion requirement is not the relevant inquiry. Plaintiffs' arguments to the contrary are misguided. The APA allows plaintiffs to file a lawsuit to challenge the decision of a federal agency only after they exhaust administrative remedies. *Idaho Sporting Congress*, 305 F.3d at 965; 5 U.S.C. § 704. Plaintiffs are not entitled to bypass the FDA's citizen petition process simply because they frame their challenges as under NEPA and the APA. 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. *See id*. ("[t]he rationale underlying the exhaustion requirement is to avoid premature claims and to ensure that the agency possessed of the most expertise in an area be given first shot at resolving a claimant's difficulties"). To hold otherwise would circumvent the statutory structure in place. Here, plaintiffs have failed to comply therewith.

c. Plaintiffs' Individual Interests Cannot Excuse Exhaustion

Finally, plaintiffs implore the Court to exercise its sound discretion and not require exhaustion. *See McCarthy v. Madigan*, 503 U.S. 140, 144-49 (1992). In *McCarthy*, the Supreme Court recognized three "broad sets of circumstances in which the interests of the individual weigh heavily against requiring administrative exhaustion." *Id.* at 146. Elanco responds that the Supreme Court's holding in *Darby* – that exhaustion is an element of an APA claim for judicial review – erased courts' discretion in APA cases to excuse failure to exhaust based on judicially-created exceptions. Specifically, where a statute or regulation mandates exhaustion, Elanco argues that exhaustion is no longer subject to judicial discretion post-*Darby*. Plaintiffs are only able to cite a single APA case post-*Darby* where a court waived an exhaustion requirement. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F.Supp. 20, 31 (D.D.C. 1997) (declining to require exhaustion on a preliminary injunction based on a showing of irreparable harm if plaintiffs were forced to engage in the administrative process). The Court does not read *Bracco Diagnostics* to endorse plaintiffs' view, especially considering the decision does not address the implications of *Darby*. Rather, the more reasonable interpretation is that the court unfortunately overlooked *Darby*'s command that administrative remedies created by regulation and statute must be exhausted. By contrast, several circuit and district courts have considered *Darby* and its progeny in this context and concluded that courts no longer have discretion to excuse failure to exhaust mandatory administrative remedies in APA cases. *See, e.g. Shawnee Trail Conservancy v. U.S. Dept. of Agric.*, 222 F.3d 383, 389 (7th Cir. 2000) (noting that a district court does not have "the power to waive the statutorily-mandated exhaustion requirement of the APA"); *Volvo GM Heavy Truck Corp. v. U.S. Dept. of Labor*, 118 F.3d 205, 212 (4th Cir. 1997) (noting that plaintiffs were unable to "point[] to any case, *involving a challenge under the APA*, since *Darby*, that has subjected the exhaustion requirement to judicial discretion") (emphasis in original); *Conservation Force v. Salazar*, 919 F.Supp.2d 85, 90-91 (D.D.C. 2013) (holding that regulatory exhaustion clauses could not be waived or excused). The Court finds the reasoning in these cases persuasive and concludes it cannot waive the exhaustion requirement here.

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Even if the citizen suit requirement were subject to judicial waiver, the Court would decline to excuse plaintiffs' failure to exhaust in this case. Plaintiffs argue that all three circumstances discussed by the Supreme Court in *McCarthy* are present here, namely that: (1) requiring the administrative remedy would result in undue prejudice to them later bringing a court action; (2) the FDA is not empowered to grant effective relief through the administrative process; and (3) exhaustion would be futile because the FDA is biased or has otherwise predetermined the issue. *Id*. at 146-49. The Court examines each:

First, plaintiffs contend that the citizen petition process would unduly prejudice them because they will "suffer irreparable harm" if the Court does not immediately consider their claims. (Oppo. at 12:24-25) (quoting *McCarthy*, 503 U.S. at 147). In plaintiffs' view, the citizen petition process does not guarantee a substantive response from the FDA, much less within a reasonable timeframe. The FDA regulations require a tentative response to a citizen petition be sent within 180 days, but do not mandate a time frame for a final response from the agency. *See* 21 CFR § 10.30(e)(2). Yet, by plaintiffs' own admission, they have an available remedy – proven successful – to ensure the FDA provides a final response in a timely manner: filing suit. *See* 5 U.S.C. § 706(1). The Court likewise finds plaintiffs' reliance on the FDA's delays in responding to unrelated citizen petitions unpersuasive because plaintiffs have not shown that FDA would unduly delay its response to *this* (hitherto unfiled) citizen petition raising NEPA concerns. Further, even if plaintiffs had shown delay, they must also make a showing of resulting injustice. *See McCarthy*, 503 U.S. at 147. The Court does not find plaintiffs' claims of injustice compelling given that they waited until November 2014 to file these lawsuits challenging FDA approvals issued beginning in 2008.

Second, plaintiffs argue that the citizen petition process would be ineffective because it cannot result in the remedies they seek. Plaintiffs claim that any "after-the-fact" NEPA review the FDA performs as a result of a citizen petition would be inadequate. (Oppo. at 22:7-10.) This Court's review, however, would be similarly limited. Judicial review at this juncture would be even more limited to the extent that the FDA has not yet developed an administrative record, utilizing its specialized expertise, addressing plaintiffs' concerns. The FDA citizen petition

process is the appropriate procedural mechanism for plaintiffs to raise its contentions in the first instance, before seeking judicial review. In response, the agency may withdraw/vacate the FDA approvals – the remedy sought by plaintiffs – should it conclude that new evidence or changed circumstances require new NEPA review. *See* 21 U.S.C. § 360b(e)(1). Plaintiffs' argument that the FDA cannot provide effective relief fails.

Lastly, with respect to whether "pursuit of administrative remedies would be a futile gesture," plaintiffs contend that the futility exception applies because the FDA is biased and has predetermined the result. *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 564 (9th Cir. 1992) (internal quotations omitted); *see McCarthy*, 503 U.S. at 148. In support thereof, plaintiffs point to a document they claim shows the "bias and the predetermined nature of [FDA's] decision making process in the Administrative Record." (Oppo. at 19:8-9) (citing Dkt. No. 25, Administrative Record at FDA_002420.) The Court recognizes the troubling nature of this document, which states:

> The Office of New Animal Drug Evaluation (ONADE) policy stipulates that EAs will not be required for Animal Drug Availability Act (ADAA) combinations regardless of whether extraordinary circumstances exist, as long as the sponsor claims a categorical exclusion, cites the correct CFR code, and states that to their knowledge no extraordinary circumstances exist.

(Dkt. No. 25.) At this juncture, the Court does not have a sufficient record in front of it to determine whether any dereliction of duty has occurred and will not speculate on same. Plaintiffs have not made a showing 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. Accordingly, the Court remains convinced that the prudent course requires it to allow the FDA its opportunity to resolve plaintiffs' grievances administratively. *See Idaho Sporting Congress*, 305 F.3d at 965 ("[t]he rationale underlying the exhaustion requirement is to avoid premature claims and to ensure that the agency possessed of the most expertise in an area be given first shot at resolving a claimant's difficulties").

For these reasons, the Court finds it inappropriate to relieve plaintiffs of their obligation to exhaust administrative remedies with the FDA before seeking judicial review.

C. The Exhaustion Requirement Was Not Waived By FDA

In response to FDA's late joinder in Elanco's motion, plaintiffs argue that the FDA waived its right to challenge plaintiffs' claims based on failure to exhaust. Specifically, plaintiffs argue that FDA violated 21 CFR section 10.45(b) because it did not move to dismiss in the first instance. Section 10.45(b) provides in pertinent part:

> If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or 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.

According to plaintiffs, "[a]llowing FDA to ignore its own regulations as a means of arguing that Plaintiffs ignored FDA regulations would lead to an illogical and erroneous result." (Dkt. No. 80 at 4:15-17.) The Court does not agree. FDA's regulations do not require that it seek *immediate* dismissal to preserve an exhaustion defense, as plaintiffs argue. While FDA's decision not to raise plaintiffs' failure to exhaust on a motion to dismiss frustrated the efficiency of this motion practice, it hardly constituted waiver. FDA preserved its right to raise exhaustion as an affirmative defense by including it in its answers to the complaints. (*See* Dkt. Nos. 38, 59.)

Likewise, the Court does not agree with plaintiffs' position that FDA must file its own motion to dismiss because Elanco lacks Article III standing to raise exhaustion alone. As discussed above, *Darby* established that exhaustion is an element of the cause of action under the APA. Plaintiffs have not articulated why Elanco must suffer injury arising out of plaintiffs' failure to exhaust in order to argue that plaintiffs have failed to plead a necessary element of their cause of action. The Court cannot discern any bar to Elanco bringing this motion, especially in light of FDA's (albeit tardy) agreement that plaintiffs must exhaust.

III. LEAVE TO AMEND

Leave to amend is liberally granted. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Chodos v. West Pub. Co.*, 292 F.3d 992, 1003 (9th Cir. 2002). One exception to this general rule of

permissiveness, however, is where amendment would be futile. *Foman*, 371 U.S. at 182; *Smith v. Pac. Props. & Dev. Corp.*, 358 F.3d 1097, 1101 (9th Cir. 2004). The Court finds that it would be futile to grant leave to amend here because plaintiffs' claims cannot proceed until they exhaust their administrative remedies with the FDA.

IV. CONCLUSION

Plaintiffs failed to exhaust their NEPA challenges pursuant to the APA, 5 U.S.C. section 704, and therefore may not yet bring this action in this Court. The Court **GRANTS** Intervenor Elanco's motion to dismiss.

Although the Court finds that plaintiffs cannot prosecute their claims at this juncture, a stay pending exhaustion (including periodic reviews) would allow the Court to monitor the progress of administrative review. Accordingly, the parties are hereby **ORDERED TO SHOW CAUSE** why the Court should not stay the case pending exhaustion. The parties shall meet and confer and file a JOINT STATEMENT on their positions regarding a stay within fourteen (14) days of the date of this Order.

This Order terminates Dkt. No. 58.

IT IS SO ORDERED.

Dated: November 5, 2015

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE

United States District Court
Northern District of California