Emily Johnson Henn (CA Bar No. 269482)
COVINGTON & BURLING LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065-1418
Telephone: (650) 632-4700
Fax: (650) 632-4800
Email: ehenn@cov.com

Attorney for Intervenor-Defendant
ELANCO ANIMAL HEALTH

Additional Counsel Listed on Signature Page

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE CENTER FOR FOOD SAFETY, *et al.*,

Plaintiffs,

and

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

Plaintiffs,

v.

MARGARET A. HAMBURG, *et al.*,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Consolidated Case Nos. 4:14-cv-04932-YGR and 14-cv-4933-YGR

NOTICE OF MOTION AND MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO EXHAUST ADMINISTRATIVE REMEDIES

Date: **July 28, 2015**

Time: **2:00 p.m.**

Dept: Oakland, Courtroom 1
Judge: Hon. Yvonne Gonzalez Rogers

NOTICE OF MOTION

Please take notice that on **July 28, 2015**, at **2:00 p.m.**, or as soon thereafter as the matter may be heard before the Honorable Yvonne Gonzalez Rogers, United States Judge, in Courtroom 1 of the United States Courthouse, 1301 Clay Street, Oakland, California 94612, Intervenor-Defendant Elanco Animal Health ("Elanco") will, and hereby does, move the Court to dismiss the Complaints for failure to exhaust administrative remedies in the above-captioned matter, as required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 704.

POINTS AND AUTHORITIES

STATEMENT OF FACTS

As plaintiffs state in the first paragraph of their complaints, they bring this action to "challenge" the Food and Drug Administration's ("FDA") "approval" of eleven new applications of animal drugs containing ractopamine hydrochloride ("ractopamine"). *See Ctr. for Food Safety, et al. ("CFS") v. Hamburg, et al.*, No. 4:14-cv-04932, Complaint (Dkt. No. 1); *The Humane Soc'y of the U.S., et al.* ("*Humane Soc'y*") *v. Hamburg, et al.* , No. 4:14-cv-04933, Complaint (Dkt. No. 1). Plaintiffs allege that FDA approved these drugs "without conducting the environmental analysis required by the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§ 4321-70." *CFS* Complaint at ¶ 1; *see also Humane Soc'y* Complaint, at ¶ 1. Plaintiffs also allege that "[m]ost of the analysis in [FDA's previous] NEPA documents is now more than fifteen years old, and fails to account for significant new circumstances and information relevant to environmental concerns raised by the use of ractopamine, particularly the current widespread use of ractopamine and other feed additives." *CFS* Complaint at ¶ 104; *Humane Soc'y* Complaint at ¶ 108.[1] Plaintiffs ask that the Court to (1) "[d]eclare that FDA's failure to comply with NEPA and the [Council on Environmental Quality] regulations before approving ractopamine-based animal drugs violates NEPA and the APA"; (2) vacate and remand FDA's approval decisions; and (3) issue "injunctive relief barring the use of ractopamine-based animal drugs until FDA complies with

[1] For purposes of a motion to dismiss, these allegations of course must be accepted as true. If this case proceeds, however, Elanco is confident that the administrative record will demonstrate the FDA did not rely on outdated information and in fact performed the required environmental review.

NEPA." *CFS* Complaint, Prayer for Relief, ¶¶ 1–3; *see also Humane Soc'y* Complaint, Prayer for Relief, ¶¶ A, B.

On February 18, 2015, Elanco moved to intervene as a defendant to protect its interest in maintaining Elanco's ability to market its products containing ractopamine. The Court granted Elanco's motion to intervene on April 1, 2015, and directed Elanco to file its proposed Rule 12 motion contending the plaintiff failed to exhaust their administrative remedies. Dkt. No. 45.[2]

ARGUMENT

Plaintiffs do not merely seek an order from this Court directing FDA to conduct a NEPA review that in their view would be adequate. Instead, they ask this Court to ***vacate*** the challenged approvals and ban the use of ractopamine pending a new NEPA review. Yet plaintiffs seek this sweeping relief without having asked the FDA Commissioner to consider the alleged changed circumstances and to determine whether withdrawal of the approvals is appropriate.

"NEPA does not provide a private cause of action for violations of its provisions." *Salmon River Concerned Citizens v. Robertson,* 32 F.3d 1346, 1353 n.13 (9th Cir. 1994). Plaintiffs therefore rely on the APA, which does provide a cause of action. *See Idaho Sporting Cong. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir. 2002). The APA "requires that plaintiffs exhaust available administrative remedies before bringing their grievances to federal court." *Id. See also* 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

[2] The Court's April 1, 2015 order also required plaintiffs to file affidavits in support of standing and authorized FDA and Elanco to file motions challenging standing under Rule 12. Dkt. No. 45. In response to that order, Plaintiffs flooded the docket with over 200 pages of declarations (with an additional 500 pages of attachments) from approximately 29 declarants in support of the plaintiffs' alleged standing. *See* Dkt. Nos. 48, 49, 51, 52. While Elanco does not contend that this mass of material is insufficient to overcome plaintiffs' minimal burden of alleging standing at the pleading stage, plaintiffs "bear[] the burden of establishing" their standing "with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). If plaintiffs' claims survive the instant motion, Elanco anticipates seeking the Court's permission to move for summary judgment on the ground that plaintiffs have failed to establish standing with necessary "specific facts." *Id*. *See also ASARCO Inc. v. Kadish*, 490 U.S. 605, 615–16 (1989) ("[T]he doctrine of standing to sue is not a kind of gaming device that can be surmounted merely by aggregating the allegations of different kinds of plaintiffs, each of whom may have claims that are remote or speculative taken by themselves.").

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. Sec'y of USDA*, 603 F.3d 1073, 1080 (9th Cir. 2010) (quoting *United Farm Workers v. Ariz. Agric. Emp't Relations Bd.*, 669 F.2d 1249, 1253 (9th Cir. 1982)); *see also Idaho Sporting Cong.*, 305 F.3d at 965. ("The 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.").

I. **FDA Regulations Require Exhaustion.**

Exhaustion applies to actions under the APA "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). FDA regulations clearly require exhaustion. 21 C.F.R. § 10.25(a) provides that "[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." *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, Nos. 5:03–00887–MRP (PLA), 5:04–00333–MRP (PLA), 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.'"). In turn, 21 C.F.R. § 10.45(b) provides that "[a] 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.***" (emphasis added) Thus, FDA regulations not only "provide an opportunity for interested parties . . . to participate in the regulatory process through the submission of a citizen petition," they in fact "*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).[3]

[3] Indeed, an article published in the journal of the American Bar Association's Section of Environment, Energy and Resources states that an effort to raise NEPA issues with FDA "begins by filing a citizen petition to the Commissioner of Food and Drugs." Shawna Bligh, *Pharmaceuticals in*

(continued…)

The failure to exhaust this remedy warrants dismissal. *See Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 358 F. App'x 179, 180–81 (D.C. Cir. 2009) (finding that appellants failed to exhaust their administrative remedies where they "filed no such citizen petition with FDA"); *Dietary Supplement Coalition, Inc. v. Sullivan*, 796 F. Supp. 441, 446 (D. Or. 1991) (granting motion to dismiss where plaintiffs had not exhausted their administrative remedies by filing a citizen petition with FDA); *IMS Ltd. v. Califano*, 453 F. Supp. 157, 160 (C.D. Cal. 1977) (same).

Plaintiffs are suing to vacate FDA's approval of the eleven identified ractopamine products. Vacation of these approvals would cause them to be withdrawn or suspended. The Federal Food, Drug, and Cosmetic Act (FDCA), however, provides specific and exclusive standards and procedures for the withdrawal or suspension of a new animal drug approval (NADA). FDCA, § 512(e)(1), 21 U.S.C. § 360b(e)(1). This statute provides in relevant part:

> (1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—
>
> > (A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A) of this section; [or]
> >
> > (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, . . . evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) of this section applies to such drug.
>
> * * *
>
> If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

Surface Waters: Use of NEPA, NATURAL RESOURCES & ENVIRONMENT Volume 24, Number 2 (Fall 2009), *available at* http://www.session.com/news/PharmaceuticalsInSurfaceWatersUseOf%20NEPA.pdf.

A citizen petition provides the required mechanism for plaintiffs to seek the relief they want from FDA in the first instance. If they believe that "experience or scientific data" or "new evidence" show that ractopamine is not safe, they are free to present that evidence to FDA through a citizen petition and ask for the withdrawal of the approvals. Indeed if plaintiffs believe that ractopamine presents "an imminent hazard to the health of man or of [] animals," they can seek immediate suspension of the approvals. But under 21 C.F.R. § 10.45 they may not bring these claims to this Court until the FDA Commissioner makes a final decision on their citizen petition.

II. **Plaintiffs Failed to Exhaust Available Administrative Remedies.**

Plaintiffs do not allege that they raised their claims with FDA prior to filing the instant lawsuits. *See CFS* Complaint; *Humane Soc'y* Complaint. Accordingly, this action impermissibly seeks to deprive FDA of the opportunity to "exercise its expertise," *Buckingham*, 603 F.3d at 1080, with respect to highly technical issues and to address the alleged changed circumstances. Nor have plaintiffs alleged any grounds to excuse their failure to challenge prior approvals and bring the alleged changed circumstances to FDA's attention through citizen petitions.[4] By failing to exhaust their administrative remedies prior to filing suit, plaintiffs have failed to state a claim under the APA, and their claims must be dismissed under Fed. R. Civ. P. 12(b)(6). *See Ass'n of Am. Physicians & Surgeons*, 358 F. App'x at 180–81; *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 163–64 (D.D.C. 2011); *Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d at 21–22.

[4] Some of the plaintiffs in this case filed a citizen petition relating to ractopamine on December 20, 2012. *See* Citizen Petition, No. FDA-2012-P-1252 (Dec. 20, 2012), at 1-2, *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-1252-0001 (2012 Petition). Plaintiffs have not cited this citizen petition in their complaints, and any belated contention that the 2012 Petition exhausted administrative remedies for this case would fail. The 2012 Petition did not challenge FDA's NEPA reviews, did not cite the changed circumstances alleged in the instant complaints, and did not seek revocation of any animal drug approvals. Furthermore, even if the 2012 Petition raised the issues raised in the instant complaints, it remains under review by FDA. On June 6, 2013, FDA issued an interim response, informing petitioners that the agency "is currently considering the issues raised by [the] citizen petition" but "will require additional time to issue a final response because of the complexity and the number of issues raised in the [the] petition." FDA Interim Response, FDA-2012-P-1252-0003 (June 6, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-1252-0003. The agency further responded that it "will issue a final response to [the] citizen petition after completing the analyses of all of the legal and policy issues raised in the petition." *Id.*

CONCLUSION

For the foregoing reasons, Elanco respectfully requests that this Court grant this motion to dismiss.

Dated: June 9, 2015

Respectfully submitted,

/s/ Emily Johnson Henn

Emily Johnson Henn (CA Bar No. 269482)
COVINGTON & BURLING LLP
One Front Street
San Francisco, California 94111
Tel: (415) 591-6000
Fax: (415) 591-6091
Email: ehenn@cov.com

Mark H. Lynch (*admitted pro hac vice*)
Bradley Ervin (*admitted pro hac vice*)
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, N.W.
Washington, D.C. 20001-4956
Tel: (202) 662-6000
Fax: (202) 662-6291
Email: mlynch@cov.com
Email: bervin@cov.com

Attorneys for Intervenor-Defendant
ELANCO ANIMAL HEALTH