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2
3
4
5
6
7
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Emily Johnson Henn (CA Bar No. 269482)
COVINGTON & BURLING LLP
3000 El Camino Real
5 Palo Alto Square
Palo Alto, California 94306-2112
Telephone: (650) 632-4700
Fax: (650) 632-4800
Email: ehenn@cov.com

Bradley K. Ervin (*pro hac vice*)
Virginia A. Williamson (*pro hac vice*)
COVINGTON & BURLING LLP
One CityCenter
850 10th Street NW
Washington, DC 20001-4956
Telephone: (202) 662-6000
Fax: (202) 662-6291
Emails: bervin@cov.com
vwilliamson@cov.com

Attorneys for Intervenor-Defendant
ELANCO ANIMAL HEALTH

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

ANIMAL LEGAL DEFENSE FUND, FOOD &
WATER WATCH, and FOOD ANIMAL
CONCERNS TRUST,

Plaintiffs,

v.

ALEX AZAR, Secretary of the United States
Department of Health and Human Services;
STEPHEN HAHN, Commissioner of the United
States Food and Drug Administration; and
UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Civil Case No. 3:20-cv-03703-JCS

**ELANCO ANIMAL HEALTH'S
MOTION TO DISMISS FOR
LACK OF ARTICLE III
STANDING AND FAILURE TO
EXHAUST ADMINISTRATIVE
REMEDIES**

Date: January 14, 2021
Time: 1:30 p.m.
Dept: San Francisco, Courtroom 3
Judge: Hon. Richard Seeborg

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

	<u>Page</u>
NOTICE OF MOTION.....	1
POINTS AND AUTHORITIES	1
INTRODUCTION AND STATEMENT OF ISSUES	1
STATEMENT OF FACTS	3
ARGUMENT.....	7
I. THE COURT SHOULD DISMISS PLAINTIFFS’ CLAIMS FOR LACK OF ARTICLE III STANDING.	7
A. Plaintiffs Have Not Plausibly Alleged Cognizable Injuries In Fact.	8
B. Plaintiffs Have Not Shown That Their Alleged Injuries Are Fairly Traceable To FDA’s Alleged NEPA Violations.....	13
C. Plaintiffs Have Not Shown That Their Alleged Injuries Are Likely To Be Redressed By Relief From This Court.....	15
II. THE COURT SHOULD DISMISS, OR IN THE ALTERNATIVE, STAY THIS SUIT DUE TO PLAINTIFFS’ FAILURE TO EXHAUST MANDATORY ADMINISTRATIVE REMEDIES.	16
A. FDA Regulations And The APA Require Exhaustion Of The Agency’s Mandatory Citizen Petition Administrative Remedy.	17
B. Plaintiffs’ Claims Should Be Dismissed Because Plaintiffs Have Not Exhausted FDA’s Mandatory Administrative Remedy.....	18
C. In The Alternative, A Stay Of Proceedings Is Appropriate To Allow Plaintiffs To Exhaust The Mandatory Citizen Petition Remedy.	22
III. PLAINTIFFS’ FIRST CLAIM FOR RELIEF SHOULD BE DISMISSED FOR FAILURE PROPERLY TO REQUEST RELIEF PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 8 AND 12(b)(6).....	22
CONCLUSION.....	24

TABLE OF AUTHORITIES

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

<u>Cases</u>	<u>Page(s)</u>
<i>Allen v. Wright</i> , 468 U.S. 737 (1984).....	15
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	7, 23
<i>Ass’n of Am. Physicians & Surgeons, Inc. v. FDA</i> , 358 F. App’x 179 (D.C. Cir. 2009).....	20
<i>Ass’n of Flight Attendants-CWA, AFL-CIO v. Chao</i> , 493 F.3d 155 (D.C. Cir. 2007).....	17
<i>Azizi v. United States</i> , No. 15-cv-07456-CAS, 2015 WL 6755193 (C.D. Cal. Nov. 4, 2015).....	23
<i>Banks v. Warner</i> , No. 94-56732, 1995 WL 465773 (9th Cir. Aug. 7, 1995).....	6
<i>Biotics Research Corp. v. Heckler</i> , 710 F.2d 1375 (9th Cir. 1983).....	19
<i>Bowen v. Massachusetts</i> , 487 U.S. 879 (1988).....	17
<i>Buckingham v. Sec’y of USDA</i> , 603 F.3d 1073 (9th Cir. 2010).....	17, 21
<i>Cent. & S.W. Servs., Inc. v. EPA</i> , 220 F.3d 683 (5th Cir. 2000).....	11
<i>Clapper v. Amnesty Int’l USA</i> , 568 U.S. 398 (2013).....	<i>passim</i>
<i>Clouser v. Espy</i> , 42 F.3d 1522 (9th Cir. 1994).....	19
<i>Ctr. for Biological Diversity v. U.S. Dep’t of Interior</i> , 563 F.3d 466 (D.C. Cir. 2009).....	13
<i>Ctr. for Biological Diversity v. U.S. Env’t Protection Agency</i> , 937 F.3d 533 (5th Cir. 2019).....	8, 10, 12, 14
<i>Ctr. for Food Safety v. Hamburg</i> , 142 F. Supp. 3d 898 (N.D. Cal. 2015).....	1, 17

1 *Ctr. for Food Safety v. Hamburg,*
 2 696 F. App’x 302 (9th Cir. 2017).....1, 3, 20, 22

3 *DaimlerChrysler Corp. v. Cuno,*
 4 547 U.S. 332 (2006).....7

5 *Daniel v. Nat’l Park Serv.,*
 6 891 F.3d 762 (9th Cir. 2018)13

7 *Darby v. Cisneros,*
 8 509 U.S. 137 (1993).....17, 18

9 *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.,*
 10 590 F. Supp. 2d 1282 (C.D. Cal. 2008)16

11 *Fed. Power Comm’n v. Colo. Interstate Gas Co.,*
 12 348 U.S. 492 (1955).....17, 19

13 *Finn v. City of Boulder City,*
 14 No. 14-cv-1834-JAD, 2015 WL 2186497 (D. Nev. May 6, 2015).....23

15 *Fla. Audubon Soc’y v. Bentsen,*
 16 94 F.3d 658 (D.C. Cir. 1996).....12

17 *Gulf Restoration Network v. Bernhardt,*
 18 No. 18-cv-1674-RBW, 2020 WL 1930470 (D.D.C. April 21, 2020).....15

19 *Havens Realty Corp. v. Coleman,*
 20 455 U.S. 363 (1982).....7

21 *Hicks v. PGA Tour, Inc.,*
 22 897 F.3d 1109 (9th Cir. 2018)5

23 *Hong v. Read,*
 24 No. 19-cv-00086-RGK, 2020 WL 4342539 (C.D. Cal. April 3, 2020).....23

25 *Hunt v. Wash. State Apple Adver. Comm’n,*
 26 432 U.S. 333 (1977).....7

27 *Levine v. Vilsack,*
 28 587 F.3d 986 (9th Cir. 2009)16

Lewis v. Casey,
 518 U.S. 343 (1996).....7

Lojas v. Washington,
 347 F. App’x 288 (9th Cir. 2009)23

Los Angeles v. Lyons,
 461 U.S. 95 (1983).....11

1 *Lujan v. Defs. of Wildlife*,
 2 504 U.S. 555 (1992)..... *passim*

3 *Myers v. Bethlehem Shipbuilding Corp.*,
 4 303 U.S. 41 (1938).....17

5 *N. Air Cargo v. U.S. Postal Serv.*,
 6 674 F.3d 852 (D.C. Cir. 2012).....23

7 *N.Y. Regional Interconnect, Inc. v. FERC*,
 8 634 F.3d 581 (D.C. Cir. 2011).....9

9 *Nat’l Res. Def. Council v. EPA*,
 10 735 F.3d 873 (9th Cir. 2013)9

11 *Nuclear Info. & Res. Serv. v. Nuclear Reg. Comm’n*,
 12 457 F.3d 941 (9th Cir. 2006)16

13 *Okanogan Highlands All. v. Williams*,
 14 No. 97-cv-806-JE, 1999 WL 1029106 (D. Or. Jan. 12, 1999)11, 14, 15

15 *Ries v. Hornell Brewing Co.*,
 16 No. 10-cv-1139-JF, 2010 WL 2943860 (N.D. Cal. July 23, 2010)6

17 *Salmon River Concerned Citizens v. Robertson*,
 18 32 F.3d 1346 (9th Cir. 1994)16

19 *Salmon Spawning v. Gutierrez*,
 20 545 F.3d (9th Cir. 2008)15

21 *Shawnee Trail Conservancy v. USDA*,
 22 222 F.3d 383 (7th Cir. 2000)17

23 *Smith v. Pac. Props. and Dev. Corp.*,
 24 358 F.3d 1097 (9th Cir. 2004)7

25 *Steel Co. v. Citizens for a Better Env’t*,
 26 523 U.S. 83 (1998).....2, 7, 8, 15

27 *Summers v. Earth Island Inst.*,
 28 555 U.S. 488 (2009).....10, 12

Susan B. Anthony List v. Driehaus,
 573 U.S. 149 (2014).....9, 11

ThermoLife Int’l, LLC v. Gaspari Nutrition, Inc.,
 648 F. App’x 609 (9th Cir. 2016)19

Tri-Bio Labs, Inc. v. United States,
 836 F.2d 135 (3d Cir. 1987)19

1 *Tyler v. Cuomo*,
 2 236 F.3d 1124 (9th Cir. 2000)13

3 *U.S. Postal Serv. v. Gregory*,
 4 534 U.S. 1 (2001).....15

5 *Unemployment Comp. Comm’n of Territory of Alaska v. Aragan*,
 6 329 U.S. 143 (1946).....20

7 *United States v. L.A. Tucker Truck Lines, Inc.*,
 8 344 U.S. 33 (1952).....20

9 *W. Watersheds Project v. Kraayenbrink*,
 10 632 F.3d 472 (9th Cir. 2011)13

11 *Wash. Env’tl Council v. Bellon*,
 12 732 F.3d 1131 (9th Cir. 2013)14

13 *Weinberger v. Bentex Pharms., Inc.*,
 14 412 U.S. 645 (1973).....19

15 *Woodford v. Ngo*,
 16 548 U.S. 81 (2006).....17, 21, 22

17 **Statutes**

18 5 U.S.C. § 701.....18

19 5 U.S.C. § 704.....1, 17, 18

20 21 U.S.C. § 301.....1

21 21 U.S.C. § 360b.....19, 23

22 33 U.S.C. § 1311.....14

23 42 U.S.C. § 4321.....1

24 **Regulations**

25 21 C.F.R. § 10.3.....18

26 21 C.F.R. § 10.25.....2, 18, 20

27 21 C.F.R. § 10.35.....5, 18, 20

28 21 C.F.R. § 10.45.....2, 18, 20

21 C.F.R. § 25.52.....19

21 C.F.R. § 514.115.....19, 20

1 40 C.F.R. § 412.114

2 **Rules**

3 Federal Rule of Civil Procedure 81, 2, 23, 24

4 Federal Rule of Civil Procedure 121, 2, 23, 24

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1 **NOTICE OF MOTION**

2 **Please take notice** that on January 14, 2021, at 1:30 p.m., or as soon thereafter as the
3 matter may be heard before the Honorable Richard Seeborg, United States District Judge, in
4 Courtroom 3 of the United States Courthouse, 450 Golden Gate Avenue, San Francisco,
5 California 94102, Intervenor-Defendant Elanco Animal Health (“Elanco”) will, and hereby does,
6 move the court for an order dismissing the First Amended Complaint filed by Plaintiffs Animal
7 Legal Defense Fund (“ALDF”), Food & Water Watch (“FWW”), and Food Animal Concerns
8 Trust (“FACT”) (collectively, “Plaintiffs”) for lack of Article III standing; failure to exhaust
9 mandatory administrative remedies as required by the Administrative Procedure Act (“APA”), 5
10 U.S.C. § 704; and failure sufficiently to plead a claim for relief pursuant to Federal Rules of Civil
11 Procedure 8 and 12(b)(6). In the alternative, Elanco requests that the Court stay this matter
12 pending Plaintiffs’ exhaustion of their administrative remedies, as required by Food and Drug
13 Administration (“FDA”) regulations and the APA.

14 **POINTS AND AUTHORITIES**

15 **INTRODUCTION AND STATEMENT OF ISSUES**

16 Asserting purported violations of the National Environmental Policy Act (“NEPA”), 42
17 U.S.C. §§ 4321, *et seq.*, and the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C.
18 §§ 301, *et seq.*, Plaintiffs filed suit under the APA challenging FDA approvals of the animal drug
19 lubabegron, which is administered to animals in feed and known under the trade name Experior.
20 Plaintiffs claim that FDA’s approvals of Experior should be vacated and all use of Experior barred
21 until FDA conducts further reviews of Experior’s safety, effectiveness, and potential
22 environmental impacts.

23 Plaintiffs’ lawsuit mirrors ALDF’s prior challenge to FDA’s approval of a different
24 approved Elanco animal drug that is also administered in feed, ractopamine. The district court
25 dismissed that complaint for failure to exhaust the citizen petition review procedures required by
26 FDA regulations, *see Ctr. for Food Safety v. Hamburg*, 142 F. Supp. 3d 898 (N.D. Cal. 2015),
27 and, on appeal, the Ninth Circuit directed ALDF “to comply with the FDA’s citizen petition
28 requirement” before proceeding in court, *Ctr. for Food Safety v. Hamburg*, 696 F. App’x 302, 304

1 (9th Cir. 2017). But Plaintiffs here did not heed that instruction, and have proceeded with their
2 claims in this Court without first exhausting FDA’s citizen petition review procedures. *See* 21
3 C.F.R. § 10.25(a); *id.* § 10.45(b). The doctrine of administrative exhaustion therefore precludes
4 judicial review of Plaintiffs’ claims until Plaintiffs comply with the administrative procedures
5 mandated by FDA’s regulations.

6 Plaintiffs’ claims should also be dismissed on two additional, independent grounds. *First*,
7 Plaintiffs’ claims should be dismissed for lack of Article III standing. To have standing to sue,
8 Plaintiffs must plausibly allege (and ultimately prove) that they suffer a cognizable injury that is
9 fairly traceable to FDA’s alleged statutory violations, and likely to be redressed by an order from
10 this Court vacating approval of Experior. *See, e.g., Steel Co. v. Citizens for a Better Env’t*, 523
11 U.S. 83, 102–03 (1998). Reflecting the fact that Experior is not yet on the market, Plaintiffs’
12 Amended Complaint asserts only future injuries that could occur *if* Experior becomes available
13 for sale, *if* feedlot operators then use Experior in ways that result in discharges into the
14 environment, and *if* those discharges adversely affect Plaintiffs’ members. Because those
15 hypothetical injuries rely on lengthy, speculative chains of causation, they are insufficiently
16 imminent to satisfy Article III’s requirements. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398,
17 409 (2013). Plaintiffs’ FDCA and NEPA claims must therefore be dismissed.

18 Plaintiffs’ NEPA claims further fail to satisfy Article III’s causation and redressability
19 requirements. Because Plaintiffs’ alleged environmental injuries from the future discharge of
20 Experior at industrial cattle feedlots hinge upon regulatory actions (or inaction) of the
21 Environmental Protection Agency (“EPA”), Plaintiffs’ challenge to FDA’s NEPA review lacks
22 the causal and remedial connections necessary to satisfy Article III.

23 *Second*, Plaintiffs’ challenge to FDA’s denial of ALDF’s petition for an administrative
24 stay (“Stay Petition”) should be dismissed for failure adequately to plead a claim for relief.
25 Federal Rules of Civil Procedure 8 and 12(b)(6) require a plaintiff to set forth both the legal
26 theories and relief requested for each claim asserted in a Complaint. Plaintiffs’ contention that
27 FDA improperly denied ALDF’s Stay Petition, however, alleges only that the denial provides
28 Plaintiffs an exhausted final agency action subject to judicial review, *see* First Am. Compl.

1 (“FAC”) (Dkt. No. 30), First Claim for Relief, ¶¶ 4, 6, not that any relief—either vacatur of the
2 denial decision or a stay of the effective date of Experior’s approval—is due for the alleged legal
3 violation. Absent an appropriate request for relief, the claim cannot proceed.

4 Viewed collectively and individually, Plaintiffs’ claims are legally deficient, and should
5 be dismissed. In the alternative, the Court should stay this litigation “to allow [Plaintiffs] to
6 comply with the FDA’s citizen petition requirement.” *Ctr. for Food Safety*, 696 F. App’x at 304.

7 STATEMENT OF FACTS

8 Plaintiffs challenge FDA’s approval of New Animal Drug Applications (“NADAs”) for
9 Experior, a drug approved for use in cattle alone and in combination with certain antibiotics, that
10 reduces ammonia gas emissions in animals’ waste. FAC ¶¶ 1, 4, 12; *see also* Declaration of Karen
11 Smith, Ph.D (Dkt. No. 18-1), ¶ 4. Plaintiffs allege that FDA approved Experior without following
12 NEPA’s procedural requirements for review of potential environmental impacts, and without
13 adequately determining Experior’s safety and effectiveness in its target animals as required by the
14 FDCA. *See, e.g.*, FAC ¶ 2.

15 Plaintiffs first allege that FDA’s environmental analysis of Experior’s future use violated
16 NEPA by failing to account for “poor manure management conditions” and EPA’s
17 “underregulat[ion]” of concentrated animal feeding operations (“CAFOs”) where Experior may
18 be used. *Id.* ¶ 154. Plaintiffs contend that, while FDA disclosed the possibility that Experior may
19 enter the environment through land application of manure and corresponding runoff, FDA did not
20 consider “several known risks of environmental contamination due to CAFO manure management
21 practices that will enable Experior to permeate the environment.” *Id.* ¶¶ 149–50. In Plaintiffs’
22 view, NEPA requires FDA to consider, among other things, that “manure can be stored in unlined
23 lagoons that are susceptible to leakage, overflow, or rupture, any of which could lead to
24 groundwater and soil contamination” and that “uneaten medicated feed” may also contaminate
25 groundwater and soil. *Id.* ¶ 150. Taken as whole, Plaintiffs allege that FDA’s approvals of
26 Experior “exacerbat[e] the existing animal, public, and environmental health effects of the CAFO
27 industry.” *Id.* ¶ 120.

1 Plaintiffs further assert that FDA’s approval of Experior—which Plaintiffs recognize has
2 not yet become available in the marketplace, *see id.* ¶ 33—has injured their members and
3 supporters. *See id.* ¶¶ 19–35. According to Plaintiffs, some of their members “live, work, and
4 recreate near and downstream from cattle feedlots that *may* give their cows Experior.” *Id.* ¶¶ 19,
5 26, 28, 30 (emphasis added). Plaintiffs contend that their members are “concerned” that there is
6 a “risk that Experior will migrate from feedlots and contaminate waterways and groundwater,”
7 *id.* ¶ 20, and that their members’ enjoyment of the environment is therefore “diminished by their
8 concern and the increased risk of harm Experior presents for wildlife and their habitat,” *id.* ¶ 21.
9 To contend with this concern, Plaintiffs allege that some of their members have altered or will
10 alter whether and how they use the waterways. *See, e.g., id.* ¶¶ 21–24. For example, Plaintiffs
11 assert that one ALDF member enjoys boating on the Mississippi River “but is hesitant to engage
12 in other activities such as kayaking and swimming in the river in the future because these activities
13 involve being in contact with the river and therefore more exposed to Experior.” *Id.* ¶ 24.
14 Similarly, Plaintiffs allege that a FACT member who lives near Lake Michigan currently “avoids
15 swimming in the waterway due to concerns about the health impacts of contaminants” and his
16 “knowledge that feedlots near Lake Michigan may begin to use Experior heightens his concerns
17 and would lead him to avoid swimming even if other more easily detectable contaminants in the
18 waterway decrease.” *Id.* ¶ 31. And Plaintiffs contend that a FWW member who enjoys visiting
19 conservation areas in Idaho has already “paused plans to purchase a paddleboard to use on
20 waterways near her because of her concerns about direct exposure to Experior-contaminated water
21 downstream.” *Id.* ¶ 28. Plaintiffs assert that the member “will be even more apprehensive to
22 invest in this activity,” “[i]f Experior [is] released into these waterways.” *Id.*

23 Plaintiffs also assert that their members are “concerned” about the human health impacts
24 of consuming beef from cows that may be treated with Experior. *See, e.g., id.* ¶¶ 22–24, 26–27.
25 “To alleviate their concerns,” Plaintiffs say their members “will be forced to source and consume
26 beef that is raised without Experior” and they “will pay premiums to purchase beef raised without
27 Experior” or will “simply be unable to find and source beef that is raised without Experior.” *Id.*
28 ¶ 22.

1 Plaintiffs further allege that FDA’s approval decisions violated the FDCA by relying on
2 studies that are, in Plaintiffs’ estimation, inadequate to assess Experior’s safety and effectiveness
3 in target animals. *Id.* ¶¶ 132–48. In particular, Plaintiffs contend that the studies relied upon by
4 FDA “contained inadequate experimental conditions to simulate feedlots,” “were based on small
5 sample sizes,” and “did not look adequately at biologically plausible and probable adverse events”
6 such as “lameness and overheating.” *Id.* ¶¶ 132–34. Plaintiffs also allege that FDA improperly
7 “dismissed” other concerns about Experior’s safety, and otherwise relied on studies allegedly
8 marred by “a certain amount of data manipulation” regarding Experior’s effectiveness. *Id.*
9 ¶¶ 132–48.

10 Prior to filing this lawsuit, “Plaintiff ALDF submitted a . . . Petition for Stay” of FDA’s
11 “approval of NADA 141-508 for Experior and the corresponding” NEPA review documents
12 because, in ALDF’s view, “Experior has not been shown to be safe and effective,” and Experior
13 has “the potential . . . to cause significant harm to the environment” *Id.* ¶¶ 125–26. The
14 other two Plaintiffs in this suit—Food & Water Watch and Food Animal Concerns Trust—did not
15 join in ALDF’s stay application and have not taken any action before FDA with respect to the
16 claims they assert here.

17 On May 20, 2019, FDA denied ALDF’s Stay Petition, concluding “that the Petition did
18 not meet the conditions set out in 21 C.F.R. § 10.35(e) requiring issuance of a stay.” FAC ¶ 128.
19 The agency explained that “[d]uring the new animal drug review process, FDA thoroughly
20 reviewed the NADA for Experior and determined the drug met the standards for approval under
21 the [FDCA] and FDA regulations.” FDA Denial Letter, at 3 (May 20, 2019).¹ Among other

22
23 ¹ Both ALDF’s Stay Petition and FDA’s Denial Letter are available on the federal government’s
24 regulatory website. *See* Requests that the FDA stay approval of New Animal Drug Application
25 141-508 for Experior™ (lubabegron Type A medicated article) and the corresponding
26 Environmental Assessment and Finding of No Significant Impact (Docket No. FDA-2018-P-
27 4656), available at <https://www.regulations.gov/docket?D=FDA-2018-P-4656> (last visited
28 October 29, 2020). In reviewing a motion to dismiss, this Court “can consider exhibits attached
to the Complaint or matters properly subject to judicial notice,” as well as “documents whose
contents are alleged in a complaint and whose authenticity no party questions, but which are not
physically attached to the . . . pleading.” *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109, 1117 (9th Cir.
2018) (citations and quotations omitted). Plaintiffs’ Complaint alleges the contents of ALDF’s

1 things, FDA reasoned that ALDF’s Stay Petition repeatedly failed to “provide any specific data
2 or information in support of” its assertions that FDA inadequately considered the potential health
3 or environmental effects of approving Experior. *Id.* at 9; *see also id.* (finding that Stay Petition
4 “does not contain an explanation of, or support for, the concern” with food safety); *id.* at 10 (“The
5 [Stay] Petition also asserts, without providing any support, that beta-agonists are ‘known to
6 increase aggression and hyperactivity in animals[.]’”); *id.* at 12 (Stay Petition’s “assertion that the
7 approval of Experior™ will lead to a denser packing of feedlots . . . is unsupported anywhere in
8 the [Stay] Petition”); *id.* at 14 (finding “the [Stay] Petition failed to provide support for the
9 assertion that the daily manure production number used in the Experior™ [environmental
10 assessment] is underestimated”).

11 More than a year after FDA denied ALDF’s Stay Petition—and eighteen months after
12 FDA’s initial approval of the NADA for Experior—Plaintiffs filed the instant lawsuit. *See* Compl.
13 (Dkt. No. 1). On September 29, 2020, Plaintiffs filed their First Amended Complaint. *See*
14 *generally* FAC. In Plaintiffs’ view, ALDF’s “timely petition to stay exhausts administrative
15 remedies,” *id.*, First Claim for Relief, ¶ 4 (citing 21 C.F.R. § 10.45(c)), and “FDA’s denial of . . .
16 ALDF’s [Stay] Petition . . . is final agency action subject to judicial review under the APA,” *id.*
17 ¶ 6 (citing 5 U.S.C. § 704). To remedy the allegedly unlawful approval of Experior, Plaintiffs ask
18 this Court to (1) “[v]acate FDA’s decision to approve Experior unless and until it complies with
19 the FDCA, NEPA, and the APA”; and (2) “[i]ssue preliminary and permanent injunctive relief
20 barring the use of Experior until FDA complies with the FDCA, NEPA, and the APA.” *Id.*,
21 Request for Relief, ¶¶ 3–4.

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26 Stay Petition and FDA’s Denial Letter, and this Court may take judicial notice of government
27 records and materials available on government websites. *See, e.g., Banks v. Warner*, No. 94-
28 56732, 1995 WL 465773, at *1 (9th Cir. Aug. 7, 1995) (“It is entirely proper for a court to take
judicial notice of records and reports of administrative agencies.”); *Ries v. Hornell Brewing Co.*,
No. 10-cv-1139-JF, 2010 WL 2943860, at *5 n.3 (N.D. Cal. July 23, 2010) (concluding that
document available on FDA website “is a matter of public record and is judicially noticeable”).

1 On August 25, 2020, Elanco moved for leave to intervene in this matter to protect its
2 interest in the approval of its NADA for Experior. Mot. for Intervention (Dkt. No. 18). The Court
3 granted Elanco’s motion on September 24, 2020. Order (Dkt. No. 25).

4 ARGUMENT

5 I. THE COURT SHOULD DISMISS PLAINTIFFS’ CLAIMS FOR LACK OF 6 ARTICLE III STANDING.

7 Standing is a constitutional prerequisite to the exercise of federal judicial power, and thus
8 constitutes “an essential and unchanging part of the case-or-controversy requirement of Article
9 III.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). For a plaintiff to have standing,
10 (1) “there must be alleged (and ultimately proved) an injury in fact—a harm suffered by the
11 plaintiff”; (2) “there must be causation—a fairly traceable connection between the plaintiff’s
12 injury and the complained-of conduct of the defendant”; and (3) “there must be redressability—a
13 likelihood that the requested relief will redress the alleged injury.” *Steel Co.*, 523 U.S. at 102–03
14 (quotation marks omitted). Plaintiffs bear the burden of demonstrating Article III standing and
15 must support each element of their standing “with the manner and degree of evidence required at
16 [each] successive stag[e] of the litigation.” *Lujan*, 504 U.S. at 561; *see also Ashcroft v. Iqbal*, 556
17 U.S. 662, 678 (2009) (explaining that, at the motion to dismiss stage, “a complaint must contain
18 sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face”
19 (quotation marks omitted)). Further, because “standing is not dispensed in gross,” *Lewis v. Casey*,
20 518 U.S. 343, 358, n.6 (1996), plaintiffs are required to establish standing for “each claim [they]
21 seek to press,” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Where, as here,
22 organizations bring suit on behalf of their members, they must show that the members would have
23 standing in their own right to sue. *Hunt v. Wash. State Apple Adver. Comm’n*, 432 U.S. 333, 343
24 (1977).²

25 ² An organization may also bring suit on its own behalf for injuries it has sustained. *See Havens*
26 *Realty Corp. v. Coleman*, 455 U.S. 363, 379 n.19 (1982). To do so, the organization must allege
27 (and ultimately show) “frustration of its organizational mission” and “diversion of its resources
28 to combat” the adverse effects of the challenged government action. *Smith v. Pac. Props. and*
Dev. Corp., 358 F.3d 1097, 1105 (9th Cir. 2004). Plaintiffs’ First Amended Complaint makes no

1 Plaintiffs' claims for relief do not satisfy this foundational burden. As detailed below,
2 Plaintiffs' alleged injuries are not cognizable because they are neither actual nor imminent.
3 Moreover, for purposes of their NEPA claim, Plaintiffs' alleged injuries are neither fairly
4 traceable to FDA's alleged NEPA violations in approving use of Experior, nor would they be
5 redressed by an order from this Court vacating FDA's approvals and remanding them for further
6 agency NEPA review. Because Plaintiffs have failed to demonstrate standing, their claims must
7 be dismissed. *See, e.g., Steel Co.*, 523 U.S. at 94.

8 **A. Plaintiffs Have Not Plausibly Alleged Cognizable Injuries In Fact.**

9 To establish injury-in-fact, a plaintiff must show "an invasion of a legally protected
10 interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or
11 hypothetical." *Lujan*, 504 U.S. at 560. "In environmental cases, courts must carefully distinguish
12 between injury to the [plaintiff] and injury to the environment." *Ctr. for Biological Diversity v.*
13 *U.S. Env'tl Protection Agency*, 937 F.3d 533, 537 (5th Cir. 2019). "Article III standing requires
14 injury to the" plaintiff, "[i]njury to the environment is insufficient." *Id.* Although a cognizable
15 injury may be linked to a plaintiff's interests—aesthetic, recreational, or scientific—in the
16 environment, "such environmental interests cannot support an injury in fact unless they have been
17 actually harmed or imminently will be." *Id.*

18 While "imminence is concededly a somewhat elastic concept," the Supreme Court has
19 emphasized that "it cannot be stretched beyond its purpose, which is to ensure that the alleged
20 injury is not too speculative for Article III purposes." *Clapper*, 568 U.S. at 409 (quotation marks
21 omitted). "By ensuring a future injury is not 'too speculative,' the imminence requirement
22 'reduce[s] the possibility of deciding a case in which no injury would have occurred at all.'" *Ctr.*
23 *for Biological Diversity*, 937 F.3d at 537 (quoting *Lujan*, 504 U.S. at 564 n.2). For that reason,
24 mere "allegations of possible future injury are not sufficient." *Clapper*, 568 U.S. at 409 (brackets
25 and quotation marks omitted). Instead, when a party's allegations of injury rest on future harm,
26

27 _____
28 allegation that any Plaintiff has diverted or anticipates diverting resources to counteract alleged
effects of FDA's approval of Experior, so Plaintiffs have not established organizational standing.

1 standing arises only if that harm is “‘certainly impending,’ or there is a ‘substantial risk’ that the
 2 harm will occur.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper*,
 3 568 U.S. at 409); *see also Nat’l Res. Def. Council v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013)
 4 (“[A]n injury is ‘actual or imminent’ where there is a ‘credible threat’ that a probabilistic harm
 5 will materialize.”). Plaintiffs’ alleged injuries fail to meet the imminence requirement for at least
 6 three reasons.

7 *First*, Plaintiffs’ theory of injury “stacks speculation upon hypothetical upon speculation,
 8 which does not establish an ‘actual or imminent’ injury.” *N.Y. Regional Interconnect, Inc. v.*
 9 *FERC*, 634 F.3d 581, 587 (D.C. Cir. 2011). Plaintiffs acknowledge that Experior has not become
 10 available in the marketplace, *see* FAC ¶ 33, and do not allege that it will imminently enter the
 11 market or that a date has been set for Experior sales to begin. Nevertheless, Plaintiffs allege that
 12 FDA’s approval of Experior will harm their members and supporters at some unidentified point
 13 in the future because they “live, recreate, and eat fish caught downstream from cow feedlots” and
 14 are “concerned” about “the risk that Experior will migrate from feedlots and contaminate
 15 waterways and groundwater.”³ *Id.* ¶ 20. Because of this “concern,” Plaintiffs say their members
 16 will face diminished enjoyment of “seeing wildlife in areas downstream from cow feedlots,” *id.*
 17 ¶ 21, and experience “fear” about the human health effects of swimming in or consuming animals
 18 from those waterways, *id.* ¶ 23. Plaintiffs assert that their members will “need to” conduct
 19 themselves differently to contend with these concerns—some will be “hesitant to engage in”
 20 activities such as swimming in waterways near cow feedlots, *id.* ¶ 24; others will “drive long
 21

22
 23 ³ Plaintiffs assert that some of their members have already altered their conduct in response to the
 24 possibility that Experior will enter the market, be used at cow feedlots near their homes, and
 25 somehow enter and contaminate the environment beyond the feedlots. *See, e.g.*, FAC ¶ 28
 26 (alleging that a FWW member has “paused plans to purchase a paddleboard to use on waterways
 27 near her because of her concerns about direct exposure to Experior-contaminated water
 28 downstream from cattle feedlots”). Any injuries Plaintiffs’ members have suffered in preparation
 for Experior’s possible, future entry onto the market are necessarily self-inflicted and insufficient
 to establish standing. *See Clapper*, 568 U.S. at 416 (plaintiffs “cannot manufacture standing
 merely by inflicting harm on themselves based on their fear of hypothetical future harm that is
 not certainly impending”).

1 distances . . . to purchase beef from suppliers that will not use Experior,” *id.* ¶ 24; and still others
2 will “pay premiums to purchase beef raised without Experior,” *id.* ¶ 22.

3 Before Plaintiffs’ members face any actual environmental harms from the use of Experior,
4 however, their Amended Complaint makes clear that a lengthy and speculative chain of events
5 must occur: Elanco would have to begin marketing Experior; feedlots near the waterways that
6 Plaintiffs’ members frequent would have to use Experior in their cow feed; those same feedlots
7 would have to mismanage cow waste such that it could enter the environment beyond the feedlot;
8 the cow waste from those feedlots would have to actually enter the environment; that waste would
9 have to contain some amount of Experior; any residual amount of Experior that entered the
10 waterways would have to reach the areas Plaintiffs’ members use at times when they are using
11 those areas; and any residual amount of Experior that entered the waterways would have to be
12 capable of causing harm to the environment, humans, or animals. *See Ctr. for Biological*
13 *Diversity*, 937 F.3d at 538 (“Courts cannot simply presume pollution discharged in one place will
14 affect would-be plaintiffs everywhere.”); *id.* at 540 (explaining that Article III requires a
15 “temporal-nexus” linking alleged environmental injuries to challenged pollutant discharges).
16 While it may be *possible* to satisfy all of these contingencies, “that speculation does not suffice”
17 to establish Article III injury because “[s]tanding . . . is not an ingenious academic exercise in the
18 conceivable[.]” *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009) (quotation omitted)
19 (attenuated chain of possibilities insufficient for procedural right claim).

20 The injuries Plaintiffs claim their members will suffer to avoid consuming beef containing
21 residual levels of Experior are equally speculative. Plaintiffs allege that ALDF “has members and
22 supporters who consume beef purchased from grocery stores and restaurants, which *can be*
23 sourced from feedlots that *will likely* use Experior.” FAC ¶ 22 (emphasis added). However,
24 Plaintiffs offer no basis for how they know from which feedlots their local stores and restaurants
25 source their beef and no basis supporting their claim that those feedlots are likely to use Experior.
26 Moreover, Plaintiffs’ assertions that their members “will drive long distances, sometimes two
27 hours, to purchase beef from a supplier that will not use Experior,” FAC ¶ 24; “will pay premiums
28 to purchase beef raised without Experior, *id.* ¶ 22; and “will be unable to consistently find and

1 source beef that will be guaranteed to be raised without Experior,” *id.* ¶ 22, are wholly speculative.
2 Given that Experior is not on the market, Plaintiffs cannot know where Experior will be used,
3 whether grocery stores near Plaintiffs’ members will sell beef from cows raised with or without
4 Experior, and how much more it will cost to buy beef from cows raised without Experior.
5 Plaintiffs’ speculation does not amount to any imminent injury, as required by Article III.

6 Nor do Plaintiffs plausibly allege any basis for asserting that they face a substantial risk
7 that *all* of these events will come to pass—much less that their feared injuries are “certainly
8 impending.” *Driehaus*, 573 U.S. at 158; *see also Clapper*, 568 U.S. at 398 (courts “have been
9 reluctant to endorse standing theories that require guesswork as to how independent
10 decisionmakers will exercise their judgment”); *cf. Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683,
11 700–01 (5th Cir. 2000) (allegations that bulk waste products disposed of in a landfill might
12 “somehow” enter the town’s water supply were insufficient to establish Article III injury).
13 Plaintiffs’ assertions that their members “need” to make changes to their recreational activities,
14 diets, or purchasing habits in response to “fears” or “concerns” about Experior also miss the mark.
15 A party invoking federal jurisdiction “cannot manufacture standing merely by inflicting harms on
16 themselves based on their fears of hypothetical future harm that is not certainly impending.”
17 *Clapper*, 568 U.S. at 416. Such injuries “are not fairly traceable” to the agency action that
18 Plaintiffs allege created their fear. *Id.* “[O]therwise, an enterprising plaintiff would be able to
19 secure a lower standard for Article III standing simply by making an expenditure based on a
20 nonparanoid fear.” *Id.* Any self-imposed restrictions Plaintiffs’ members have adopted in
21 response to their fears and concerns about the potential, future use of Experior do not establish
22 Article III injury. *See Los Angeles v. Lyons*, 461 U.S. 95 (1983), 107 n.8 (“It is the reality of the
23 threat of [impending] injury that is relevant to the standing inquiry, not the plaintiff’s subjective
24 apprehensions.”).

25 *Second*, Plaintiffs have not established *when* they will experience any actual injury as a
26 result of FDA’s approval of Experior. Plaintiffs acknowledge that Experior is not yet
27 commercially available, *see* FAC ¶ 33, but allege that their members face “concrete and ongoing”
28 harms because FDA has approved Experior and “actively allows it to be used and marketed.” *id.*;

1 *see also id.* ¶ 26 (alleging that members will be harmed “when Experior is widely distributed in
2 the marketplace” without providing any indication regarding when that will occur). Plaintiffs’
3 members do not, however, face *imminent* harm merely because FDA allows the marketing and
4 use of a drug that is not currently being marketed or used. The complete absence of allegations
5 regarding when Experior will enter the market and when Plaintiffs’ members would be adversely
6 affected by Experior dictates that Plaintiffs have not plausibly alleged the type of imminent harm
7 that Article III requires.

8 *Third*, Plaintiffs’ allegations fall short of establishing that their members will recreate in
9 areas affected by FDA’s approval of Experior. “[T]o establish standing, plaintiffs must show that
10 they ‘use the area affected by the challenged activity and not an area roughly in the vicinity of’
11 the activity.” *Summers*, 555 U.S. at 499 (quoting *Lujan*, 504 U.S. at 566). Yet Plaintiffs do not
12 say that their members intend to use any particular area where Experior will be used. Instead,
13 Plaintiffs generally allege that their members live or recreate near feedlots that “*may* begin to use
14 Experior” and speculate that there is a “*risk* that Experior will migrate from feedlots and
15 contaminate the waterways and groundwater” that their members plan to use. FAC ¶¶ 20, 31
16 (emphases added). At most, Plaintiffs’ allegations amount to a claim that they will use waterways
17 in the vicinity of feedlots where Experior *might* (or might not) end up being used. These
18 contentions are insufficient to establish that Plaintiffs face imminent injury due to FDA’s approval
19 of Experior. *See, e.g., Ctr. for Biological Diversity*, 937 F.3d at 538 (“[P]etitioners cannot simply
20 assert some interest somewhere within a large geographic area.”); *cf. Fla. Audubon Soc’y v.*
21 *Bentsen*, 94 F.3d 658, 667 (D.C. Cir. 1996) (“[A] court may not assume that the areas used and
22 enjoyed by a prospective plaintiff will suffer all or any environmental consequences that the rule
23 itself may cause.”).

24 Because Plaintiffs have not plausibly alleged that they or their members face actual or
25 imminent injuries the Court should dismiss Plaintiffs’ claims for lack of standing.

B. Plaintiffs Have Not Shown That Their Alleged Injuries Are Fairly Traceable To FDA’s Alleged NEPA Violations.

Along with adequately alleging an actual or imminent injury, a plaintiff also must show that any such alleged injuries are “fairly traceable” to the challenged action of the defendant, and not “the result of the independent action of some third party not before the court.” *Tyler v. Cuomo*, 236 F.3d 1124, 1132 (9th Cir. 2000).⁴ For that reason, where, as here, the plaintiff “is not the object of” the challenged “government action or inaction, ‘standing is not precluded, but it is ordinarily substantially more difficult to establish.’” *Ctr. for Biological Diversity v. U.S. Dep’t of Interior*, 563 F.3d 466, 477 (D.C. Cir. 2009) (quoting *Lujan*, 504 U.S. at 562). Here, the “choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict,” *Lujan*, 504 U.S. at 562, sever the necessary chain of causation between FDA’s NEPA review of its decision to approve Experior and the environmental injuries alleged in the Complaint.

Plaintiffs principally assert that their environmental injury flows from FDA’s allegedly deficient NEPA review because Experior “will enter the environment through manure, and FDA fails to identify several known risks of environmental contamination due to CAFO manure management practices that will enable Experior to permeate the environment.” FAC ¶ 149. *See also id.* ¶¶ 136–37; *id.* ¶ 74 (alleging discharges of animal feed that degrade water quality); ¶ 97 (alleging water pollution from CAFOs). But Plaintiffs concede that the allegedly injurious manure management and CAFO discharges are separately regulated by “state and federal law[s]” administered by agencies *other than* FDA, and over whom FDA has no control. *Id.* ¶ 154. These intervening authorities render “[t]he line of causation” from FDA’s actions to CAFO discharges

⁴ While Article III’s “causation and redressability requirements are relaxed” in a NEPA case “[o]nce a plaintiff has established an injury in fact,” *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 485 (9th Cir. 2011) (emphasis added), Plaintiffs have failed to show a cognizable injury-in-fact in this case. *See supra* pp. 8–12. Regardless, even when “relaxed,” causation remains “no less essential to the ‘irreducible constitutional minimum’ of standing.” *Daniel v. Nat’l Park Serv.*, 891 F.3d 762, 767 (9th Cir. 2018).

1 too “attenuated” for standing purposes. *Wash. Env’tl Council v. Bellon*, 732 F.3d 1131, 1141 (9th
2 Cir. 2013).⁵

3 In particular, Plaintiffs acknowledge EPA’s primary statutory role enforcing the Clean
4 Water Act’s prohibition of the discharge of any pollutants into a waterway from any point source,
5 including CAFOs. See FAC ¶ 154. Indeed, absent EPA’s issuance of a permit authorizing and
6 regulating the discharge of such a pollutant to minimize or prevent environmental damage, the
7 Clean Water Act prohibits such discharges. See 33 U.S.C. § 1311(a); *id.* § 1342(a); *id.* § 1362(14)
8 (defining “concentrated animal feeding operation[s]” as point sources under the Clean Water Act).
9 EPA has accordingly issued regulations governing CAFO discharges to minimize potential
10 impacts on water quality and public health. See, e.g., 40 C.F.R. §§ 412.1, *et seq.* (describing,
11 among other things, best management practices for management of manure from a variety of farm
12 animals). In short, “the pollutants that will cause [Plaintiffs’] assumed injuries” are traceable to
13 EPA’s regulation of CAFO discharges, not FDA’s approval of Experior. *Ctr. for Biological*
14 *Diversity*, 937 F.3d at 544. Article III causation is not satisfied where, as here, the allegedly
15 injurious action is taken “pursuant to some other authority or in violation of law” enforced by
16 another agency. *Id.*

17 Plaintiffs’ allegation that “EPA notoriously underregulates the CAFO industry,” FAC
18 ¶ 154, does not shift responsibility for CAFO discharges from EPA to FDA or cause Plaintiffs’
19 alleged environmental injuries to result from FDA’s alleged failure to consider this EPA
20 “underregulat[ion]” in its NEPA analysis. Rather, “it is reasonable for an agency to presume that
21 other agencies enforce applicable requirements according to the law.” *Okanogan Highlands All.*
22 *v. Williams*, No. 97-cv-806-JE, 1999 WL 1029106, at *6 (D. Or. Jan. 12, 1999). In other words,

23
24 ⁵ Plaintiffs’ related allegations that approval of Experior injures their members because it “is likely
25 to increase cow herd size and density at feedlots, and . . . could encourage construction of new
26 feedlots,” Compl., ¶ 34, are too speculative to establish causation. See, e.g., *Clapper*, 568 U.S. at
27 414 (holding that “speculative chain of possibilities does not establish that injury . . . is fairly
28 traceable” to challenged government action). Plaintiffs allege no facts to support their assumption
that approval of Experior will cause CAFOs to increase the density of herds or construct new
facilities. See *Lujan*, 541 U.S. at 562 (explaining that it is plaintiff’s burden to demonstrate “facts
showing that [the unfettered] choices [of third parties] have been or will be made in such manner
as to produce causation and permit redressability of injury”).

1 FDA may reasonably “base its evaluation of environmental impacts on the assumption that other
2 specialized agencies with jurisdiction will enforce” laws and regulations governing CAFO
3 discharges. *Id.* at *4 (citing *No GWEN All. of Lane Cty., Inc. v. Aldridge*, 855 F.2d 1380, 1386–
4 87 (9th Cir. 1988)), *see also U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001) (“[A] presumption
5 of regularity attaches to the actions of Government agencies.”); *Gulf Restoration Network v.*
6 *Bernhardt*, No. 18-cv-1674-RBW, 2020 WL 1930470, at *11 (D.D.C. April 21, 2020) (holding
7 that agency’s NEPA analysis reasonably relied on another agency’s enforcement of its regulatory
8 authority over allegedly injurious activities).

9 Having “hinge[d]” their NEPA claim on the independent decisions of CAFOs and the
10 independent exercise of regulatory authority by EPA, *Lujan*, 504 U.S. at 562, Plaintiffs have failed
11 adequately to connect their alleged injuries to FDA’s decisions to approve Experior, or FDA’s
12 corresponding NEPA review of the potential effects that approval may have on the environment.
13 The Court should therefore dismiss Plaintiffs’ NEPA claim for lack of Article III standing.

14 **C. Plaintiffs Have Not Shown That Their Alleged Injuries Are Likely To Be**
15 **Redressed By Relief From This Court.**

16 Redressability examines the “connection between the alleged injury and the judicial relief
17 requested.” *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984). The mere fact that a court has the
18 power to issue the relief requested in a Complaint is irrelevant absent direct redress of the
19 plaintiff’s asserted injuries. In other words, “[r]elief that does not remedy the injury suffered
20 cannot bootstrap a plaintiff into federal court.” *Steel Co.*, 523 U.S. at 107.

21 In the NEPA context, a plaintiff must show that “the relief requested—that the agency
22 follow the correct procedures—may influence that agency’s ultimate decision of whether to take
23 or refrain from taking a certain action.” *Salmon Spawning v. Gutierrez*, 545 F.3d at 1226–27 (9th
24 Cir. 2008). Although relaxed in the NEPA context, the redressability requirement is “not toothless
25 in procedural injury cases.” *Id.* at 1227. Among other things, a procedural injury is not
26 redressable where, even if the plaintiff prevails, a party not before the Court remains free to
27 engage in the allegedly injurious actions and the plaintiff cannot show that the third-party would
28 refrain from taking those actions as a result of the requested judicial relief against the agency

1 defendant. *See Lujan*, 504 U.S. at 562; *see also, e.g., Levine v. Vilsack*, 587 F.3d 986, 995 (9th
2 Cir. 2009); *Nuclear Info. & Res. Serv. v. Nuclear Reg. Comm'n*, 457 F.3d 941, 955 (9th Cir. 2006)
3 (no redressability where another agency's rules had the same effect as the challenged agency
4 action).

5 Here, redressability is lacking because of the existence of third parties' intervening "broad
6 and legitimate discretion the courts cannot presume either to control or to predict." *Lujan*, 504
7 U.S. at 562 (quotation omitted). Even if the Court issues an order remanding FDA's approval
8 decisions for further NEPA analysis, as explained above EPA holds regulatory authority over the
9 CAFO manure management and discharges responsible for Plaintiffs' alleged injuries. *See supra*
10 pp. 14–15. On remand, FDA remains entitled reasonably to assume that EPA fulfills its statutory
11 and regulatory obligations, *see supra* pp. 14–15, and the Amended Complaint alleges no facts
12 suggesting that FDA would decide otherwise, *see Lujan*, 541 U.S. at 562. Given EPA's
13 intervening authority and FDA's legitimate reliance on EPA to fulfill its statutory role as the
14 primary regulator of CAFO pollution, Plaintiffs have not shown that the alleged injuries on their
15 NEPA claim are redressable in this litigation.⁶

16 **II. THE COURT SHOULD DISMISS, OR IN THE ALTERNATIVE, STAY THIS**
17 **SUIT DUE TO PLAINTIFFS' FAILURE TO EXHAUST MANDATORY**
18 **ADMINISTRATIVE REMEDIES.**

19 Plaintiffs' claims that FDA violated NEPA and the FDCA are brought pursuant to the
20 APA. *See, e.g., FAC, Claims for Relief* ¶¶ 1–26; *Salmon River Concerned Citizens v. Robertson*,
21 32 F.3d 1346, 1353 n.13 (9th Cir. 1994) ("NEPA does not provide a private cause of action for
22 violations of its provisions."); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*,
23 590 F. Supp. 2d 1282, 1287 (C.D. Cal. 2008) ("[N]o private right of action exists to redress alleged
24 violations of the FDCA.").

25
26 ⁶ This is not to say that Plaintiffs have no way of vindicating their environmental claims. To the
27 extent Plaintiffs believe EPA is not fulfilling its statutory obligations regarding regulation of
28 CAFOs, Plaintiffs may seek judicial review of EPA's actions (or omissions) directly. What
Plaintiffs may *not* do is mount a back-door challenge to those EPA actions by seeking review of
a different agency's decisionmaking. *See, e.g., Lujan*, 541 U.S. at 561–62.

1 The APA, in turn, requires exhaustion of mandatory administrative remedies prior to filing
2 suit. Because Plaintiffs have not exhausted the citizen petition administrative remedy mandated
3 by FDA regulations, Plaintiffs' claims should be dismissed, or in the alternative stayed, to allow
4 Plaintiffs to pursue the prescribed citizen petition process and allow the agency "to exercise its
5 expertise over the subject matter" asserted in Plaintiffs' claims. *Buckingham v. Sec'y of USDA*,
6 603 F.3d 1073, 1080 (9th Cir. 2010) (quoting *United Farm Workers v. Ariz. Agric. Emp't*
7 *Relations Bd.*, 669 F.2d 1249, 1253 (9th Cir. 1982)). See also *Ctr. for Food Safety*, 696 F. App'x
8 at 303–04.

9 **A. FDA Regulations And The APA Require Exhaustion Of The Agency's**
10 **Mandatory Citizen Petition Administrative Remedy.**

11 Under the doctrine of exhaustion of administrative remedies, "no one is entitled to judicial
12 relief for a supposed or threatened injury until the prescribed administrative remedy has been
13 exhausted." *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51 (1938). "Broadly
14 speaking, the doctrine of exhaustion of administrative remedies 'serves the twin purposes of
15 protecting administrative agency authority and promoting judicial efficiency.'" *Ass'n of Flight*
16 *Attendants-CWA, AFL-CIO v. Chao*, 493 F.3d 155, 158 (D.C. Cir. 2007) (quotation omitted). To
17 those ends, "[e]xhaustion gives an agency an opportunity to correct its own mistakes . . . before it
18 is haled into federal court, and it discourages disregard of [the agency's] procedures." *Woodford*
19 *v. Ngo*, 548 U.S. 81, 89 (2006) (citation omitted).

20 Section 704 of the APA codifies this bedrock common law exhaustion doctrine. See 5
21 U.S.C. § 704; *Bowen v. Massachusetts*, 487 U.S. 879, 902 (1988) ("the primary thrust of § 704
22 was to codify the exhaustion requirement"); *Shawnee Trail Conservancy v. USDA*, 222 F.3d 383,
23 388–89 (7th Cir. 2000) ("The requirement of administrative exhaustion is a traditional common
24 law doctrine that has now been codified in section 10(c) of the APA, 5 U.S.C. § 704."). In
25 "strengthen[ing] . . . the principle requiring the exhaustion of administrative remedies," *Fed.*
26 *Power Comm'n v. Colo. Interstate Gas Co.*, 348 U.S. 492, 499–500 (1955), the APA mandates
27 exhaustion "to the extent that it is required by statute or by agency rule as a prerequisite to judicial
28 review," *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). Thus, a plaintiff generally must exhaust

1 “all administrative remedies expressly prescribed by statute or agency rule” before seeking
2 judicial review pursuant to the APA. *Id.* at 146.

3 With respect to Plaintiffs’ challenges to FDA’s approval of Experior, FDA regulations
4 permit any member of the public to challenge any agency action, including the approval of a
5 NADA, via a citizen petition. The citizen petition regulation broadly permits any interested
6 person to “petition the Commissioner to issue, amend, or revoke a regulation or order, or take or
7 refrain from taking any other form of administrative action.” 21 C.F.R. § 10.25(a). Such
8 “[a]dministrative action” includes “every act . . . involved in the administration of any law by the
9 Commissioner.” 21 C.F.R. § 10.3(a). Agency regulations further require a “final administrative
10 decision” on such petitions before a party may seek judicial review, providing:

11 A request that the Commissioner take or refrain from taking any form of
12 administrative action must first be the subject of a final administrative decision
13 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.

14 21 C.F.R. § 10.45(b) (emphases added). In the meantime, “[a]n interested person may request the
15 Commissioner to stay the effective date of any administrative action,” including a stay “for an
16 indefinite time period.” 21 C.F.R. § 10.35(b).

17 Taken together, FDA’s regulations require Plaintiffs to exhaust the citizen petition process
18 set out in 21 C.F.R. § 10.25(a) before filing suit. Only then has FDA taken “final agency action”
19 on the issues raised by the Plaintiffs that is “reviewable in the courts under 5 U.S.C. 701 *et seq.*”
20 21 C.F.R. § 10.45(d). *See also Darby*, 509 U.S. at 146 (“When an aggrieved party has exhausted
21 all administrative remedies expressly prescribed by statute or agency rule, the agency action is
22 ‘final for the purposes of [§ 704]’ and therefore ‘subject to judicial review’ under the first sentence
23 [of § 704].”).

24 **B. Plaintiffs’ Claims Should Be Dismissed Because Plaintiffs Have Not**
25 **Exhausted FDA’s Mandatory Administrative Remedy.**

26 The Amended Complaint does not allege (nor could it allege) that Plaintiffs have
27 exhausted the FDA’s citizen petition procedure before filing this suit. Because Plaintiffs have not
28 completed the FDA’s mandatory citizen petition process, they have not satisfied the APA’s

1 exhaustion requirement, and their challenge “is not directly appealable” to the courts. *Clouser v.*
2 *Espy*, 42 F.3d 1522, 1532 (9th Cir. 1994) (applying Forest Service mandatory exhaustion
3 provisions). Rather, “exhaustion should be required before an aggrieved party may seek federal
4 court review”—a “requirement that plaintiffs have not satisfied” in this case. *Id.*

5 Indeed, “[t]he necessity for prior administrative consideration . . . is apparent where, as
6 here,” resolution of the issues presented “calls for the application of technical knowledge and
7 experience not usually possessed by judges.” *Fed. Power Comm’n*, 348 U.S. at 501. *See also*
8 *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 654 (1973) (“Threshold questions within the
9 peculiar expertise of an administrative agency are appropriately routed to the agency, while the
10 court stays its hand.”). Here, Plaintiffs raise issues of drug safety and effectiveness, and the health
11 of humans and animals. *See supra* pp. 3–5. These issues are core to FDA’s mission under the
12 FDCA and raise scientific and technical questions within FDA’s expertise. *See, e.g., ThermoLife*
13 *Int’l, LLC v. Gaspari Nutrition, Inc.*, 648 F. App’x 609, 612 (9th Cir. 2016) (recognizing that “the
14 FDCA protects public health by relying on the FDA’s expertise”); *Tri-Bio Labs, Inc. v. United*
15 *States*, 836 F.2d 135, 142 (3d Cir. 1987); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1376
16 (9th Cir. 1983).

17 Moreover, the relief Plaintiffs seek from this Court—vacatur of FDA’s approval of
18 Experior, and an injunction against use of Experior pending completion of a renewed approval
19 procedure on remand—would be available through the administrative citizen petition process.
20 Animal and human health concerns—if adequately demonstrated by Plaintiffs through a citizen
21 petition—would permit FDA to suspend or withdraw approval of Experior. *See* 21 U.S.C.
22 § 360b(e)(1); *id.* § 360b(i); 21 C.F.R. § 514.115(a), (b) (authorizing FDA to suspend or withdraw
23 approval of a NADA if, among other things, “[e]xperience or scientific data” or “[n]ew evidence”
24 show that the drug is unsafe or poses “an imminent hazard to the health of man or of the animals”
25 using the approved drug or feed). Likewise, FDA regulations make clear that post-approval
26 comments on environmental aspects of the NADA also “can form the basis for the Agency to
27 consider beginning an action to withdraw the approval” 21 C.F.R. § 25.52(b). Upon
28

1 withdrawal of approval of the NADA, the regulation authorizing use of the drug “shall be
2 revoked.” 21 C.F.R. § 514.115(e).

3 That ALDF filed a petition with FDA to *stay approval* of Experior does not, as Plaintiffs
4 claim, “exhaust[] administrative remedies,” FAC, First Claim for Relief, ¶ 4 (citing 21 C.F.R.
5 § 10.45(c)), and create a “final agency action subject to judicial review under the APA,” *id.* ¶ 6
6 (citing 5 U.S.C. § 704). While ALDF filed a petition for a stay pursuant to 21 C.F.R. § 10.35(b),
7 the Amended Complaint is silent as to *any* action taken by Plaintiffs to comply with the citizen
8 petition requirement. Exhaustion of Plaintiffs’ present claims requires “a [citizen] petition
9 submitted under § 10.25(a)” “before any legal action is filed in a court complaining of the action
10 or failure to act.” 21 C.F.R. § 10.45(b). *See supra* pp. 5–6.

11 To the extent that ALDF’s Stay Petition implicates exhaustion, that petition may exhaust
12 a claim in this Court “*requesting a stay of administrative action.*” 21 C.F.R. § 10.45(c) (emphasis
13 added). But Plaintiffs request no such remedy. Rather, Plaintiffs ask this Court to “[v]acate
14 FDA’s decision to approve Experior unless and until it complies with the FDCA, NEPA, and the
15 APA”; and (2) “[i]ssue preliminary and permanent injunctive relief barring the use of Experior
16 until FDA complies with the FDCA, NEPA, and the APA.” FACT, Request for Relief, ¶¶ 3–4.
17 Plaintiffs therefore ask this Court to effect a withdrawal of FDA’s decision approving Experior
18 and a corresponding bar against Experior’s use pending FDA’s further review on remand—the
19 remedies available through the citizen petition process. *See supra* pp. 17–18. As the Ninth Circuit
20 confirmed three years ago in ALDF’s prior challenge to FDA’s approval of a different drug that
21 is also approved to be administered in feed, such claims “[r]equir[e]” Plaintiffs “*to file a citizen*
22 *petition.*” *Ctr. for Food Safety*, 696 F. App’x at 303 (emphasis added). *See also Ass’n of Am.*
23 *Physicians & Surgeons, Inc. v. FDA*, 358 F. App’x 179, 181 (D.C. Cir. 2009) (explaining that
24 FDA regulations “explicitly require” exhaustion of the citizen petition process before an interested
25 person may seek judicial review of the agency’s action).

26 Moreover, “[a] reviewing court usurps the agency’s function when it sets aside the
27 administrative determination upon a ground not theretofore presented.” *Unemployment Comp.*
28 *Comm’n of Territory of Alaska v. Aragan*, 329 U.S. 143, 155 (1946). *See also United States v.*

1 *L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) (“[C]ourts should not topple over
2 administrative decisions unless the administrative body not only has erred, but has erred against
3 objection made at the time appropriate under its practice.”). Although ALDF’s Stay Petition
4 raised various challenges to FDA’s approval of Experior, it did not allow “the expert agency
5 [Congress] created,” *Hynson, Westcott & Dunning*, 412 U.S. at 627, “an opportunity to correct
6 any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or
7 premature judicial intervention,” *Buckingham*, 603 F.3d at 1080 (citation omitted). To the
8 contrary, ALDF’s Stay Petition merely requested a stay of the Experior approval, not (as Plaintiffs
9 seek here) a substantively different outcome regarding that approval decision. Moreover, ALDF’s
10 Stay Petition presented only brief, vague, and often “unsupported” contentions regarding the state
11 of science regarding Experior’s effects on human health, animal health, and the environment. *See*
12 *supra* pp. 5–6. The Amended Complaint is no different, *see, e.g.*, FAC ¶ 137 (alleging that
13 unidentified “[s]tudies indicate that animals fed Experior experienced poor appetite and other
14 gastrointestinal issues”), and further underscores the necessity of directing Plaintiffs’ claims to
15 the citizen petition procedure mandated by FDA’s regulations.

16 The other two Plaintiffs—Food & Water Watch and Food Animal Concerns Trust—have
17 an even weaker claim to exhaustion, having failed to file *anything* regarding their claims at the
18 FDA. The Amended Complaint speaks only to ALDF’s Stay Petition and does not mention
19 agency submissions by the remaining Plaintiffs. As a result, those Plaintiffs have not plausibly
20 alleged that they have complied with the exhaustion requirement.

21 In short, ALDF chose to pursue an administrative remedy that does not exhaust the claims
22 asserted in the Amended Complaint, and the other Plaintiffs chose not to pursue any
23 administrative remedies whatsoever. The APA’s exhaustion requirement, however, directs
24 Plaintiffs to pursue the precise remedy prescribed by FDA’s rules, “which means using all steps
25 that the agency holds out, and doing so *properly*[.]” *Woodford*, 548 U.S. at 90 (citation and
26 quotation omitted)). “Because exhaustion requirements are designed to deal with parties who do
27 not want to exhaust, administrative law creates an incentive for these parties to do what they
28 would otherwise prefer not to do, namely, to give the agency a fair and full opportunity to

1 adjudicate their claims.” *Id.* Dismissal of the Amended Complaint is therefore warranted for
 2 Plaintiffs’ failure properly to exhaust FDA’s prescribed citizen petition procedure.

3 **C. In The Alternative, A Stay Of Proceedings Is Appropriate To Allow Plaintiffs**
 4 **To Exhaust The Mandatory Citizen Petition Remedy.**

5 Although Plaintiffs’ failure to exhaust their administrative remedies supports dismissal, in
 6 these circumstances, the Court may nevertheless “stay further proceedings to allow [Plaintiffs] to
 7 comply with the FDA’s citizen petition requirement.” *Ctr. for Food Safety*, 696 F. App’x at 304.
 8 Such a stay “prevent[s] the premature interference with agency processes so that the agency may
 9 function efficiently . . .[,] afford the parties and the courts the benefit of its experience and
 10 expertise, and . . . compile a record which is adequate for judicial review.” *Id.* at 303 (quoting
 11 *Tamosaitis v. URS Inc.*, 781 F.3d 468, 478 (9th Cir. 2015)). Accordingly, in the event that the
 12 Court declines to dismiss the Amended Complaint for failure to exhaust, Elanco respectfully
 13 requests that the Court stay this case pending Plaintiffs’ exhaustion of the citizen petition
 14 requirement.

15 **III. PLAINTIFFS’ FIRST CLAIM FOR RELIEF SHOULD BE DISMISSED FOR**
 16 **FAILURE PROPERLY TO REQUEST RELIEF PURSUANT TO FEDERAL**
 17 **RULES OF CIVIL PROCEDURE 8 AND 12(b)(6).**

18 To the extent that Plaintiffs’ First Claim for Relief challenging FDA’s denial of ALDF’s
 19 Stay Petition, *see* FAC, First Claim for Relief, ¶¶ 1–7, cannot be further exhausted before the
 20 agency, that claim nevertheless should be dismissed because the Complaint fails to request any
 21 relief for FDA’s allegedly erroneous denial.

22 Plaintiffs’ First Claim for Relief appears primarily directed at establishing exhaustion for
 23 the entire Amended Complaint and a final agency action subject to judicial review. *See id.*, First
 24 Claim for Relief, ¶¶ 1–7 (alleging that denial of ALDF’s Stay Petition “is final agency action
 25 subject to judicial review”). *But see supra* pp. 18–22 (explaining that ALDF’s Stay Petition did
 26 not exhaust the required administrative remedies). Indeed, neither the First Claim for Relief nor
 27 Plaintiffs’ Request for Relief seeks an order setting aside FDA’s denial of ALDF’s Stay Petition,
 28 or granting a stay of the effective date of FDA’s approval of Experior as requested in ALDF’s
 Stay Petition. *See* Stay Petition, *supra* n.1, at 1. Rather, the Complaint requests vacatur of FDA’s

1 decision approving Experior, and corresponding injunctive relief barring use of Experior while
 2 FDA addresses the vacated approval. *See id.*, Relief Requested, ¶¶ 3–4. Such remedies target
 3 FDA’s allegedly erroneous *approval* of Experior in the first instance, not the *denial of a stay* of
 4 the approval’s effective date.

5 Viewed as a whole, Plaintiffs’ First Claim for Relief lacks a connected remedial request.
 6 Federal Rule of Civil Procedure 8 requires a complaint to “clearly and concisely” set out “what
 7 legal theories plaintiff relies upon, and what relief plaintiff seeks *as to each claim.*” *Azizi v. United*
 8 *States*, No. 15-cv-07456-CAS, 2015 WL 6755193, at *3 (C.D. Cal. Nov. 4, 2015) (emphasis
 9 added). Likewise, under Federal Rule of Civil Procedure 12(b)(6), “only a complaint that states
 10 a plausible claim for relief survives a motion to dismiss.” *Iqbal*, 556 U.S. at 679 (citing *Bell*
 11 *Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). Plaintiffs’ failure to seek a remedy directed
 12 at denial of ALDF’s Stay Petition therefore warrants dismissal. *See, e.g., Azizi*, 2015 WL
 13 6755193, at *3 (dismissing complaint without prejudice); *Hong v. Read*, No. 19-cv-00086-RGK,
 14 2020 WL 4342539, at * n.1 (C.D. Cal. April 3, 2020) (explaining that a complaint must “contain
 15 a ‘short and plain statement’ of each claim for relief ‘showing that [plaintiff] is entitled to relief’
 16 (quoting Fed. R. Civ. P. 8(a), (d)); *Finn v. City of Boulder City*, No. 14-cv-1834-JAD, 2015 WL
 17 2186497, at *2 (D. Nev. May 6, 2015) (“Each claim should be set out in a separate cause of action
 18 that contains all facts supporting its essential elements and states the specific relief requested.”).
 19 *Cf. Lojas v. Washington*, 347 F. App’x 288, 290 (9th Cir. 2009) (affirming dismissal of § 1983
 20 claim for failure to request prospective injunctive relief cognizable on such a claim).⁷

21 _____
 22 ⁷ Plaintiffs’ request for injunctive relief, moreover, is superfluous in this case. Plaintiffs claim
 23 that FDA’s approval of Experior was arbitrary and capricious in violation of the APA and that
 24 vacatur of the approval is therefore warranted. *See, e.g.,* FAC First Claim for Relief, ¶ 7; *id.*,
 25 Second Claim for Relief, ¶ 13, *id.*, Third Claim for Relief, ¶ 25, *id.*, Relief Requested, ¶ 3.
 26 Because neither a new animal drug nor animal feed containing a new animal drug may be used
 27 absent FDA approval, *see* 21 U.S.C. § 360b(a)(1)–(2); *id.* § 360b(b)(1) (requiring new animal
 28 drug applicant to submit reports of investigations “to show whether or not such drug is safe and
 effective for use”), the FDCA and a vacatur order would result in the ban on use of Experior that
 Plaintiffs’ requested injunctive relief seeks. Plaintiffs’ request for an injunction is therefore
 illusory. *See N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) (“It was quite
 anomalous to issue an injunction. When a district court reverses agency action and determines

1 Even assuming that Plaintiffs' challenge to the denial of ALDF's Stay Petition satisfies
2 the pleading requirements of Rules 8 and 12(b)(6), because Plaintiffs' other unexhausted claims
3 challenge the underlying approval of Experior, in the interest of efficiency the Court should
4 likewise stay Plaintiffs' First Claim pending exhaustion of Plaintiffs' remaining claims.

5 **CONCLUSION**

6 For the foregoing reasons and those set forth in the Federal Defendants' brief, Elanco
7 respectfully requests that this Court dismiss the Plaintiffs' claims or, in the alternative, stay this
8 action pending Plaintiffs' exhaustion of FDA's mandatory citizen petition procedure.

9
10 Dated: October 29, 2020

Respectfully submitted,

11 /s/ Emily Johnson Henn
12 Emily Johnson Henn (CA Bar No. 269482)
13 COVINGTON & BURLING LLP
14 3000 El Camino Real
15 5 Palo Alto Square
16 Palo Alto, California 94306-2112
17 Tel: (650) 632-4700
18 Fax: (650) 632-4800
19 Email: ehenn@cov.com

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27 that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal
28 error and then remand to the agency, because the role of the district court in such situations is to
act as an appellate tribunal.”).