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10 **THE UNITED STATES DISTRICT COURT**  
11 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

12  
13 ANIMAL LEGAL DEFENSE FUND,  
FOOD & WATER WATCH, and FOOD  
14 ANIMAL CONCERNS TRUST,

15 *Plaintiffs,*

16 v.

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

21 *Defendants.*  
22

Case No. 3:20-cv-03703-RS

**FIRST AMENDED COMPLAINT FOR  
DECLARATORY AND INJUNCTIVE  
RELIEF**

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**INTRODUCTION**

1  
2 1. Plaintiffs Animal Legal Defense Fund (“ALDF”), Food & Water Watch  
3 (“FWW”), and Food Animal Concerns Trust (“FACT”) challenge the United States Food and  
4 Drug Administration’s (“FDA” or “the Agency”) approval of and subsequent denial of a petition  
5 to stay approval of Experior™ (lubabegron Type A medicated article), a beta 3-adrenergic  
6 agonist/antagonist (“ $\beta$ 3-AA”) manufactured by Elanco US, Inc., that allegedly results in less  
7 ammonia gas released from the waste produced by cows raised for beef.

8 2. FDA approved Experior on November 6, 2018, in violation of the Federal Food,  
9 Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301-399, the National Environmental Policy  
10 Act (“NEPA”), 42 U.S.C. §§ 4321-70, and therefore the Administrative Procedure Act (“APA”),  
11 5 U.S.C. § 706. This approval will allow producers to administer this controversial new drug to  
12 the nearly 100 million cows raised for beef in the United States despite the facts that FDA did  
13 not properly announce the approval in the Federal Register, Experior has not been shown to be  
14 safe and effective, and FDA did not adequately consider the drug’s environmental impacts.

15 3. Beta-adrenergic agonist/antagonist (“ $\beta$ -AA”) drugs like Experior are linked to  
16 significantly higher mortality rates in cows due to a host of fatal respiratory, cardiac, and  
17 digestive issues, in addition to significant behavioral issues that make animals more likely to be  
18 abused and suffer in ways that directly impact food safety and worker health. These drugs also  
19 contaminate the environment.

20 4. Though the negative effects of beta-agonist drugs are widely known and well  
21 established, the beta-agonist subtype to which Experior belongs is the least-studied of all  
22 beta-agonist drugs; the specific mechanism of the drug is not yet understood, even by the drug’s  
23 sponsor.

24 5. The documents submitted by the drug sponsor as part of its application for  
25 approval of Experior illustrate the likelihood it will cause the negative effects typically  
26 associated with beta-agonists, and also raise significant uncertainty about additional effects both  
27 intended and unintended.  
28

1           6.       The FDCA requires FDA to refuse any new animal drug application where the  
2 application does not show that a drug is safe for use, where FDA has “insufficient information”  
3 to determine whether a drug is safe for use, or where there is a lack of substantial evidence that  
4 the drug will have the effect it purports. FDA must deny—not approve—applications for  
5 approval of new animal drugs that cannot be supported by available science.

6           7.       At best, the documents provided to FDA by the drug sponsor in support of its  
7 approval are insufficient to establish the drug’s safety—at worst, they show it is unsafe. These  
8 documents also fail to show that, when actually used under approved conditions, the drug will  
9 have its intended effect of reducing the release of ammonia gas.

10          8.       In approving this drug FDA also failed to consider the increased food safety and  
11 public health risk of its decision.  $\beta$ -AA drug residues end up in meat products and have been  
12 linked to human heart and respiratory issues in consumers, producers, and farm workers.  $\beta$ -AA  
13 drugs also increase the likelihood that an animal will experience injury and stress at industrial  
14 animal feeding operations—commonly known as factory farms—and at the slaughterhouse;  
15 stress depresses the immune system, making animals more susceptible to pathogens, and  
16 increases animals’ susceptibility to and shedding of zoonotic bacteria such as *salmonella*. These  
17 effects could have wide ranging implications and expose the public to increased health risks.

18          9.       The Environmental Assessment (“EA”) prepared in support of Experior’s  
19 approval also failed to adequately analyze whether the approval will have a significant impact on  
20 the environment. The EA made no meaningful attempt to address the cumulative impacts of the  
21 current rampant use of  $\beta$ -AAs and other animal drugs in cows slaughtered for food in the United  
22 States. FDA issued a Finding of No Significant Impact (“FONSI”) that did not consider any  
23 alternatives, involve the public in the review process, or explain why an Environmental Impact  
24 Statement (“EIS”) was not required under NEPA. Indeed, FDA’s FONSI admits that “both the  
25 terrestrial and aquatic environments may ultimately be affected by” Experior; yet, it failed to  
26 prepare an EIS addressing this and other potential impacts on an uncounted number of humans,  
27 hundreds of thousands of animals, and millions of acres of habitat from the multiple pathways  
28 through which Experior is discharged into the environment.

1           10.     On December 6, 2018, Plaintiff ALDF submitted a Petition for Stay of Action  
2 (“Petition”) to FDA concerning its approval of Experior. ALDF’s petition outlined the  
3 deficiencies in FDA’s approval and illustrated several things: that the approval will cause  
4 irreparable harm to Plaintiffs by allowing the use of a drug with known and unknown risks to  
5 target animal safety, human health, and the environment, and that such approval is not consistent  
6 with the public interest; that target animal safety and effectiveness and compliance with  
7 environmental laws are sound public policy grounds that support a stay; and that public health  
8 and other public interests clearly outweigh any delay that would occur while FDA conducts the  
9 adequate animal and human health safety tests and environmental review the law requires.

10           11.     FDA denied the Petition on May 20, 2019, based on the same inadequate  
11 documents it used to support its decision to approve the drug. Both the approval itself and the  
12 decision not to stay the approval violate federal law.

13           12.     On May 21, 2019, one day after denying ALDF’s Petition, FDA approved  
14 additional drugs that combine the original Experior formulation with controversial antibiotics  
15 tylosin and monensin. These combination drug approvals are tiered to, and therefore suffer from  
16 the same deficiencies as, the original Experior approval.

17           13.     The FDCA simply does not allow FDA to approve animal drugs without  
18 sufficient data to support the drug’s safety or efficacy. NEPA similarly requires FDA to  
19 thoroughly consider a drug’s effects on the environment before approval. These laws mandate  
20 that FDA thoroughly assess new drugs and their impacts *before* they are approved; they do not  
21 allow FDA and drug manufacturers to subject animals, humans, and the environment to  
22 significant harm while they continue to learn about a new drug. And the FDCA’s public notice  
23 requirement is meant to give these regulatory requirements effect.

24           14.     By failing to meet the standards required of it by either statute when it approved  
25 Experior and its progeny, FDA violated the FDCA, NEPA, the APA, and its own regulations.  
26 This Court should vacate FDA’s unlawful approval of Experior and remand this matter to FDA  
27 with instructions to carry out any approval in accordance with federal law.  
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**JURISDICTION AND VENUE**

15. This Court has jurisdiction over this action under 28 U.S.C. § 1331 (federal question).

16. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(C) because Plaintiff Animal Legal Defense Fund resides in the Northern District of California.

17. Plaintiff Animal Legal Defense Fund resides in Sonoma County. Accordingly, assignment to the San Francisco Division or the Oakland Division is proper pursuant to Civil Local Rules 3-2(c) and (d).

18. This Court may award all necessary injunctive relief pursuant to the APA, 5 U.S.C. § 706(1), and may award declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

**PARTIES**

19. Plaintiff **Animal Legal Defense Fund** (“ALDF”) is a national nonprofit membership organization founded in 1979 in Cotati, California. ALDF’s mission is to protect the lives and advance the interests of animals through the legal system. Advocating for effective oversight and regulation of the development, expansion, and pollution of the animal agriculture industry across the United States is one of ALDF’s central goals, which it achieves by filing lawsuits, administrative comments, and rulemaking petitions to increase legal protections for animals; by supporting strong animal protection legislation; and by fighting against legislation, like state “Ag Gag” laws, that are harmful to animals and communities surrounding concentrated animal feeding operations (“CAFOs”). Through these efforts, ALDF seeks to ensure transparency in the CAFO system, which is paramount to its ability to protect farmed animals and ALDF members from CAFOs’ immensely harmful effects. ALDF has more than 300,000 members and supporters throughout the United States, many of whom live near, recreate near, and closely monitor CAFOs in their communities.

20. More specifically, ALDF has individual members and supporters who live, recreate, and eat fish caught downstream from cow feedlots. These individuals are aware that FDA approved Experior without sufficient information to ensure its safety. They are concerned

1 about exposure to and are harmed by FDA's approval of Experior, i.e. the risk that Experior will  
2 migrate from feedlots and contaminate waterways and groundwater. These members are  
3 concerned about and at direct risk of human health impacts from environmental exposure to  
4 Experior.

5 21. ALDF members and supporters are also aware that FDA approved Experior  
6 without adequately studying its environmental effects. These individuals enjoy seeing wildlife in  
7 areas downstream from cow feedlots while walking, hiking, and biking. They are concerned  
8 about Experior's effects on these animals and their habitat, and therefore their enjoyment of  
9 these activities is diminished by their concern and the increased risk of harm Experior presents  
10 for wildlife and their habitat.

11 22. ALDF also has members and supporters who consume beef purchased from  
12 grocery stores and restaurants, which can be sourced from feedlots that will likely use Experior.  
13 These individuals are aware that FDA approved Experior without sufficient information to  
14 ensure its safety. To alleviate their concerns and avoid risks to their health, these members will  
15 be forced to source and consume beef that is raised without Experior from grocery stores or  
16 through direct purchases from farmers and ranchers. These members will pay premiums to  
17 purchase beef raised without Experior, such as organic or drug-free beef, or simply be unable to  
18 find and source beef that is raised without Experior. Some individual ALDF members find it  
19 both difficult and cost-prohibitive to source their meat from local farms that do not raise their  
20 animals with animal drugs like Experior, which will require them to alter their eating habits in  
21 response to their inability to source Experior-free beef. Individual ALDF members who consume  
22 beef also are concerned about and do not want to financially support farms that needlessly inflict  
23 additional negative effects on cows, and therefore will seek to buy beef raised without the use of  
24 Experior for this reason as well.

25 23. For example, one pregnant ALDF member regularly visits, and has concrete plans  
26 to continue visiting, Grapevine, Texas with her family. While there, she and her family go  
27 boating, fishing, and swimming on waterways near Grapevine. When she returns to Texas with  
28 her child, she will need to restrict these activities to avoid either of them being exposed to

1 Exporior downstream from cow feedlots. This member is also concerned that the fish her father  
2 catches in waterways downstream from cow feedlots in Texas will be contaminated by Exporior  
3 and therefore may be unsafe to eat. This member is particularly concerned about the impact that  
4 exposure to Exporior would have on her pregnancy, whether through consuming beef or  
5 fresh-caught fish, or recreating in waterways downstream from feedlots where Exporior can be  
6 used. Because of this fear, she will avoid or reduce her consumption of fresh-caught fish when  
7 she visits her father and will urge her father to do the same. She also has definite plans to source  
8 the beef she consumes in a manner that avoids potential exposure to residual levels of Exporior,  
9 which will require more of her time and money.

10 24. Another ALDF member, in Iowa, lives on the banks of the Mississippi River, and  
11 is concerned about Exporior's effects on the water quality in the river. This individual regularly  
12 engages in boating on the Mississippi River and has definite plans to continue doing so in the  
13 future, but is hesitant to engage in other activities such as kayaking and swimming in the river in  
14 the future because these activities involve being in contact with the river and therefore more  
15 exposed to Exporior. As a result of her concerns about Exporior and her desire to avoid exposure  
16 to Exporior through residues in beef, this member will drive long distances, sometimes two  
17 hours, to purchase beef from a supplier that will not use Exporior. FDA's approval of Exporior  
18 increases this individual's skepticism of the safety of beef sold in grocery stores and solidifies  
19 her need to expend additional time, effort, and money to source her beef elsewhere.

20 25. Plaintiff **Food & Water Watch** ("FWW") is a national, nonprofit membership  
21 organization that mobilizes regular people to build political power to move bold and  
22 uncompromised solutions to the most pressing food, water, and climate problems of our  
23 time. FWW uses grassroots organizing, media outreach, public education, research, policy  
24 analysis, and litigation to protect people's health, communities, and democracy from the growing  
25 destructive power of the most powerful economic interests. Combating the harms associated with  
26 industrial farm animal production, also known as factory farming, is one of FWW's priority  
27 issues. FWW is engaged in several campaigns to reduce these industrial facilities' pollution,  
28 public health threats, harms to rural communities, and animal welfare abuses through stronger

1 regulation and enforcement, increased transparency, and public education and engagement.  
2 FWW has more than a decade of experience advocating for stronger FDA oversight of food  
3 safety and of products that could harm the environment, including urging stronger oversight of  
4 antibiotics used in factory farms and challenging FDA's approval of genetically engineered  
5 salmon for human consumption. FWW communicates extensively with its members and  
6 supporters, as well as the general public, about FDA's oversight of factory farm practices and  
7 other food safety issues, including by releasing reports and fact sheets, issuing press releases and  
8 statements, publishing online news pieces, and sending emails and action alerts. FWW has more  
9 than one million members and supporters nationwide and maintains offices across the country.

10         26. FWW has members and supporters who live, work, and recreate near and  
11 downstream from cattle feedlots that may give their cows Experior. These members and  
12 supporters are aware of FDA's recent approval of Experior and are concerned about the  
13 environmental and health impacts of drugs such as Experior being released into the air and water  
14 in their communities. When Experior is widely distributed in the marketplace, these individuals  
15 will take measures to avoid exposure to Experior in their communities, such as stopping or  
16 limiting swimming in waterways and other activities they previously enjoyed. FWW members  
17 and supporters also consume beef and therefore are concerned about, and at risk of exposure to,  
18 the health risks of consuming beef containing residual levels of Experior. These members and  
19 supporters will be unable to consistently find and source beef that will be guaranteed to be raised  
20 without Experior, and therefore will potentially consume beef from grocery stores that has  
21 residual levels of Experior in it.

22         27. For example, one FWW member in Iowa has experience working on a feedlot and  
23 therefore knowledge about waste management practices at these facilities. This individual is  
24 concerned about the environmental and health impacts of the use of Experior on feedlots. This  
25 FWW member lives adjacent to fields where manure from feedlots is spread and is concerned  
26 that residual Experior in the manure will migrate onto his property and into his drinking water  
27 and could lead to increased health risks; he will be injured by the potential of health risks from  
28 exposure to Experior from feedlot waste near his property. He will also be injured by trying to

1 avoid consuming beef that might have residual levels of Experior in it or by eating beef that has  
2 residual levels of Experior in it. This member is concerned that eating beef purchased from the  
3 grocery store will expose him to Experior and lead to a higher potential risk of health issues. This  
4 member has personally witnessed how beta-agonists can adversely impact the behavior of pigs  
5 and therefore is particularly concerned about the potential health impacts of Experior, and does  
6 not want to financially support institutions that choose to administer drugs that lead to such  
7 alarming animal behavior.

8         28. Another FWW member in Idaho enjoys visiting conservation areas adjacent to  
9 and downstream from cow feedlots to recreate in water and view birds, other wildlife, and  
10 aquatic life; she has concrete plans to visit conservation areas adjacent to and downstream from  
11 cow feedlots in the future. This member is concerned about how Experior will impact the  
12 well-being of the wild animals she cares about and their ecosystems. This will diminish her  
13 enjoyment of hiking, bird-watching, and other outdoor activities. This FWW member  
14 additionally has paused plans to purchase a paddleboard to use on waterways near her because of  
15 her concerns about direct exposure to Experior-contaminated water downstream from cattle  
16 feedlots. If Experior were to be released into these waterways, she will be even more  
17 apprehensive to invest in this activity that she enjoys, and she will have to travel even further to  
18 access clean waterways. This member is also injured by the future use of Experior by feedlots  
19 because it poses a risk to her health and the health of her son when they engage in activities  
20 downstream from cattle feedlots, including kayaking, wading, and swimming.

21         29. Plaintiff **Food Animal Concerns Trust** (“FACT”) is a national nonprofit  
22 advocacy organization based in Illinois. FACT was founded in 1982 as the first U.S.  
23 organization devoted exclusively to addressing the public health problems that result from  
24 raising farm animals in confined and inhumane conditions. FACT promotes the safe and humane  
25 production of meat, milk, and eggs, and envisions and advocates for a food system in which all  
26 food-producing animals are raised in a healthy and humane manner so that everyone will have  
27 access to safe and humanely-produced food. With a particular focus on eliminating or curbing  
28 the use of antibiotics and drugs given to food-producing animals in order to protect consumers

1 from drug residues, FACT has long been concerned about both the human health impacts from  
2 the use of beta-agonist drugs and their impact on animal health and welfare. FACT advocates for  
3 responsible use of animal drugs by surveying producers and publishing reports and “score cards”  
4 to educate the public and regulators on the use of animal drugs in the food system. FACT also  
5 advocates directly to FDA for the withdrawal of beta-agonists. In 2013, FACT successfully  
6 petitioned and sued FDA to remove arsenic-containing drugs from the food supply.

7         30. Members and supporters of FACT are aware of FDA’s unlawful approval of  
8 Experior and are concerned about the resulting public health, environmental, and food safety  
9 impacts. FACT members and supporters are concerned that exposure to Experior in waterways  
10 may lead to detrimental impacts to their health, the health of others, and the health of wildlife.  
11 Additionally, some of FACT’s members and supporters eat beef purchased from grocery stores  
12 and restaurants multiple times a week and therefore may eat beef from cows that have been given  
13 Experior. These members and supporters are concerned about the potential health impacts to  
14 themselves and their family members from residual levels of Experior in beef. FACT’s members  
15 and supporters are also worried about the possibly of getting sick from beef due the increased  
16 risk of food contamination caused by cows experiencing a weakened immune system because of  
17 Experior. These members and supporters will be injured by the increased potential for health  
18 risks as a result of exposure to Experior, as well as by the diminishment of their enjoyment of  
19 activities such as going to restaurants to eat meals that contain beef, as well as cooking and  
20 eating beef at home.

21         31. One member of FACT lives directly on Lake Michigan, a waterway with  
22 documented impacts from cattle feedlot pollution, and avoids swimming in the waterway due to  
23 concerns about the health impacts of contaminants. The knowledge that the feedlots near Lake  
24 Michigan may begin to use Experior heightens his concerns and would lead him to avoid  
25 swimming even if other more easily detectable contaminants in the waterway decrease. This  
26 member also fears that FDA’s approval of Experior may financially hurt his business of selling  
27 natural drug-free beef, as he believes that increased drug use on cattle feedlots perpetuates a  
28 growing public perception that all beef is unsafe to eat and that the labeling of all beef cannot be

1 fully trusted. He worries this will contribute to the trend of decreasing demand for beef,  
2 including for the beef he sells.

3 32. Another FACT supporter is particularly concerned about how residual levels of  
4 Experior in beef may interact with prescription muscle relaxers that she must take on a regular  
5 basis. She has no way of knowing whether the beef she buys in the grocery store will have  
6 residual levels of Experior in it, and she is unable to easily source and afford local beef that is  
7 guaranteed to be drug-free. She seeks to limit her exposure to health risks but will be unable to  
8 make an informed decision about her exposure to Experior.

9 33. Each of these members and supporters of Plaintiff organizations is aware of and  
10 harmed by FDA's approval of Experior, which failed to adequately assess Experior's safety for  
11 humans and animals and its impact on the environment, including the spaces and species about  
12 which these individuals care. These harms are both individual and cumulative in nature. These  
13 harms are concrete and ongoing by virtue of the continued approval of Experior that actively  
14 allows it to be used and marketed, even if Experior has not yet become widely available in the  
15 marketplace.

16 34. Plaintiffs and their members and supporters have a strong interest in preventing  
17 FDA approval of unsafe animal drugs that may harm public health, the environment, or animal  
18 health and welfare. Plaintiffs and their members and supporters understand that Elanco intends to  
19 distribute Experior under the pretense that Experior will reduce ammonia emissions; they and  
20 their members and supporters are particularly concerned that FDA's approval of Experior will  
21 further entrench the harmful CAFO industry by making it possible for large feedlots to  
22 "greenwash" their operations by claiming lower emissions of ammonia, which is known to harm  
23 human health, rural quality of life, and the environment. They are also aware that Experior is  
24 likely to increase cow herd size and density at feedlots, which will encourage construction of  
25 new feedlots.

26 35. Plaintiffs and their members and supporters are further injured by FDA's  
27 unlawful denial of Plaintiff ALDF's Petition because, in denying the Petition, FDA deprived  
28

1 Plaintiffs and their members and supporters of an opportunity to comment on the Petition and  
2 thereby share their concerns with the Agency.

3 36. A lawful and thorough review of Experior’s animal welfare, food safety,  
4 environmental, and health impacts *before* Experior is widely distributed in the marketplace, or a  
5 Court order vacating FDA’s unlawful action, would redress Plaintiffs’ and their members’ and  
6 supporters’ injuries by providing them with accurate data on the risks that Experior poses to  
7 humans, animals, and the environment, or eliminating the risks altogether. It would also provide  
8 them an opportunity to participate in FDA’s decision-making process, as required by law.

9 37. Defendant **Alex Azar** is the Secretary of the United States Department of Health  
10 and Human Services, which includes FDA. The Secretary of the U.S. Department of Health and  
11 Human Services, “through the Commissioner” of FDA, regulates new animal drugs. 21 U.S.C.  
12 § 393(d)(2). Secretary Azar is named a Defendant solely in his official capacity.

13 38. Defendant **Steven Hahn** is the Commissioner of FDA. In that capacity, he is  
14 directly responsible for overseeing the FDA review process for the Experior application and is  
15 tasked with the authority to approve, deny, or withdraw approval for Experior upon a finding that  
16 applicable legal requirements have or have not been met. Commissioner Hahn is named as a  
17 Defendant solely in his official capacity.

18 39. Defendant **U.S. Food and Drug Administration** is a federal agency within the  
19 U.S. Department of Health and Human Services. FDA is charged with the regulation of medical  
20 products, tobacco, foods, and veterinary medicine. As described by the agency itself, FDA is  
21 responsible for protecting public health by ensuring that human and veterinary drugs are safe and  
22 effective.

### 23 **STATUTORY AND REGULATORY FRAMEWORK**

#### 24 **Federal Food, Drug, and Cosmetic Act and FDA Regulations**

25 40. In enacting the FDCA in 1938, Congress provided FDA with the authority and  
26 obligation to protect public health and safety by overseeing certain food products, drugs, and  
27 cosmetics. Through the FDCA, Congress charged FDA with “promot[ing] the public health” by  
28 ensuring that “human and veterinary drugs are safe and effective.” 21 U.S.C. § 393.

1 41. A “new animal drug” is any drug intended for use in animals that has not been  
2 used to a material extent or for a material time and is not recognized by “experts qualified by  
3 scientific training and experience” as safe and effective for use under the conditions prescribed.  
4 *Id.* § 321(v).

5 42. A new animal drug is deemed “unsafe” unless FDA has approved a new animal  
6 drug application for the drug and its use conforms to its labeling and the conditions of the  
7 approved application. *Id.* § 360b(a)(1).

8 43. The FDCA requires an applicant to submit reports to demonstrate whether its drug  
9 is “safe and effective for use.” *Id.* § 360b(b)(1)(A). The applicant must also submit “other use  
10 restrictions . . . in order to assure that the proposed use of such drug will be safe.” *Id.*  
11 § 360b(b)(1)(H). FDA regulations require an applicant to submit evidence to establish the “safety  
12 and effectiveness” of a new animal drug. 21 C.F.R. § 514.1(8).

13 44. The FDCA requires FDA to refuse any new animal drug application where: the  
14 results of “adequate tests by all methods reasonably applicable” either “show that such drug is  
15 unsafe for use under [prescribed] conditions or do not show that such drug is safe for use under  
16 such conditions”; it “has insufficient information to determine whether such drug is safe for use  
17 under such conditions”; or “there is a lack of substantial evidence that the drug will have the  
18 effect it purports or is represented to have under the conditions of use prescribed, recommended,  
19 or suggested in the proposed labeling thereof.” 21 U.S.C. § 360b(d)(1).

20 45. The FDCA does not define the phrases “safe and effective” or “safety and  
21 effectiveness,” nor the term “effective.” The statute states generally that the term “safe” “has  
22 reference to the health of man or animal.” *Id.* § 321(u). But in considering whether a drug is  
23 “safe,” FDA may consider, among other things: (1) “the cumulative effect on man or animal of  
24 such drug”; (2) “safety factors” that experts consider appropriate; and (3) whether the conditions  
25 in the proposed labeling are reasonably certain to be followed. *Id.* § 360b(d)(2). When evaluating  
26 the sufficiency of the information about a drug’s safety and effectiveness, FDA must similarly  
27 consider “(A) the probable consumption of such drug and of any substance formed in or on food  
28 because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking

1 into account any chemically or pharmacologically related substance, (C) safety factors which in  
2 the opinion of experts, qualified by scientific training and experience to evaluate the safety of  
3 such drugs, are appropriate for the use of animal experimentation data, and (D) whether the  
4 conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably  
5 certain to be followed in practice.” 21 C.F.R. § 514.111(a)(4).

6 46. The FDCA requires FDA to publish approval of new animal drug applications in  
7 the Federal Register. 21 U.S.C. § 360(i). This notice must include “conditions and indications of  
8 use of the new animal drug . . . and such other information, . . . as the Secretary deems necessary  
9 to assure the safe and effective use of such drug.” *Id.*; *see also* 21 C.F.R. § 514.105.

10 47. FDA’s authority to oversee and enforce approvals of new animal drugs is tied to  
11 the continued “safety” of a drug. A drug is considered “unsafe” post-approval if its use does not  
12 conform to the approved application. 21 U.S.C. § 360b(a)(1)(A). FDA also has authority to  
13 withdraw approval of a new animal drug if it finds that its use is “unsafe” even under the  
14 approved conditions or if the applicant makes any changes from the standpoint of “safety or  
15 effectiveness.” *Id.* § 360b(e)(1).

16 48. An interested person can, within 30 days of the approval, request that FDA stay a  
17 particular approval pending further review. 21 C.F.R. § 10.35(b). FDA’s Commissioner must  
18 grant a stay in any proceeding if all of the following apply: (1) the petitioner will otherwise  
19 suffer irreparable injury; (2) the petitioner’s case is not frivolous and is being pursued in good  
20 faith; (3) the petitioner has demonstrated sound public policy grounds supporting a stay; and  
21 (4) the delay resulting from the stay is not outweighed by public health or other public interests.  
22 *Id.* at (e)(1).

### 23 National Environmental Policy Act

24 49. NEPA is “our basic national charter for protection of the environment.” 40 C.F.R.  
25 § 1500.1(a) (2018). NEPA emphasizes the importance of comprehensive environmental analysis  
26 and requires the action agency—here, FDA—to make informed decisions by taking a “hard  
27 look” at potential environmental consequences before taking action. It also ensures that  
28

1 “environmental information is available to public officials and citizens before decisions are made  
2 and before actions are taken.” *Id.* § 1500.1(b) (2018).

3 50. All “major Federal actions significantly affecting the quality of the human  
4 environment” require the preparation of a detailed EIS by the action agency. 42 U.S.C.  
5 § 4332(2)(C). Thus, a threshold determination is whether a proposed project may “significantly”  
6 affect the environment.

7 51. Congress created the Council on Environmental Quality (“CEQ”) to implement  
8 NEPA by promulgating regulations applicable to all federal agencies. *Id.* § 4342.

9 52. CEQ’s regulations<sup>1</sup> direct agencies to prepare an EA to determine whether the  
10 proposed action will have a significant impact on the environment and warrant the preparation  
11 of an EIS. 40 C.F.R. § 1508.9 (2018). An EA must provide sufficient evidence and analysis to  
12 allow an agency to determine whether it should prepare an EIS or a FONSI.

13 53. CEQ regulations require an agency to consider the direct, indirect, and cumulative  
14 impacts of a proposed action’s impact on the environment, as well as “considerations of both  
15 context and intensity.” *Id.* §§ 1508.8, 1508.27 (2018). Context considerations include analysis of  
16 the action’s impact on affected regions, varying by the locality of the action, as well as national  
17 and societal impacts. *Id.* § 1508.27 (2018). Intensity refers to the severity of the impact, and  
18 requires the agency to consider ten factors, including, among others: beneficial and adverse  
19 impacts; public health or safety impacts; unique characteristics of the affected geographic area,  
20 such as proximity to ecologically critical areas; the degree to which the effects are likely to be  
21 highly controversial; highly uncertain risks; precedential effects; cumulatively significant  
22 impacts; and adverse effects on threatened and endangered species. *Id.*

23 54. NEPA further requires agencies to “rigorously explore and objectively evaluate  
24 all reasonable alternatives.” *Id.* § 1502.14(a) (2018); 42 U.S.C. § 4332(2)(E).

25 55. If an agency decides not to prepare an EIS, it must explain why a project will not  
26 have a significant effect on the environment. 40 C.F.R. § 1508.13 (2018).

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28 <sup>1</sup> CEQ has revised its NEPA regulations in the time since FDA approved Experior in 2018.  
The citations herein refer to the regulations that were in effect at the time of the approval.

1           56.     A new animal drug application must either contain an EA or present an analysis  
2 and justification for why the applicant believes that it qualifies for a categorical exclusion under  
3 NEPA. 21 C.F.R. § 514.1(b)(14). Consideration of this information is integral to FDA’s review  
4 of the application. *See id.* § 514.110(b)(10). FDA must reject the application if “[t]he applicant  
5 fails to submit an adequate environmental assessment . . . or fails to provide sufficient  
6 information to establish that the requested action is subject to categorical exclusion . . . .” *Id.*  
7 § 514.111(a)(9).

8           57.     FDA’s regulations categorically exclude new animal drug applications and  
9 supplemental New Animal Drug Applications from NEPA review *only if* the action does not  
10 increase the use of the drug. *Id.* § 25.33(a).

11           58.     A normally categorically excluded action requires at least an EA if “extraordinary  
12 circumstances” indicate that the proposed action “may significantly affect the quality of the  
13 human environment.” *Id.* § 25.21. FDA’s regulations cite the CEQ context and intensity  
14 regulations for examples of significant impacts and explicitly provide two examples of  
15 extraordinary circumstances: actions where “there is potential for serious harm to the  
16 environment,” and actions that adversely affect listed threatened or endangered species or their  
17 critical habitat. *Id.*

18 Administrative Procedure Act

19           59.     The APA grants a right of judicial review to “[a] person suffering legal wrong  
20 because of agency action, or adversely affected or aggrieved by agency action . . . .” 5 U.S.C.  
21 § 702.

22           60.     Under the APA, a court must “hold unlawful and set aside agency action . . .  
23 found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with  
24 law . . . .” *Id.* § 706(2)(A). An agency action is “arbitrary and capricious if the agency has relied  
25 on factors which Congress has not intended it to consider, entirely failed to consider an important  
26 aspect of the problem, offered an explanation for its decision that runs counter to the evidence  
27 before the agency, or is so implausible that it could not be ascribed to a difference in view or the  
28

1 product of agency expertise.” *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*,  
2 463 U.S. 29, 43 (1983).

3 61. Under the APA, a court must also “hold unlawful and set aside” any agency  
4 action taken that is “in excess of statutory jurisdiction, authority, or limitations, or short of  
5 statutory right.” 5 U.S.C. § 706(2)(C).

6 62. Finally, under the APA, a court shall also “hold unlawful and set aside” any  
7 agency action that was promulgated “without observance of procedure required by law.” *Id.*  
8 § 706(2)(D).

### 9 FACTS

#### 10 Beta-Agonists

11 63. Exuperior is part of the beta-adrenergic agonist/antagonist (“beta-agonist” or  
12 “ $\beta$ -AA”) family. The  $\beta$ -AA family was first described more than 60 years ago and has been  
13 divided into three subtypes:  $\beta 1$ ,  $\beta 2$ , and  $\beta 3$ . Exuperior belongs to the beta 3-phenethanolamine  
14 adrenergic agonist/antagonist (“ $\beta 3$ -AA”) subtype.

15 64. Beta-agonists are widely used in meat production in the United States due to their  
16 efficacy in increasing animal growth. For pigs alone, around 60-80% of those raised for food in  
17 the United States receive beta-agonists, amounting to tens of millions of animals each year.

18 65. Beta-agonists shift dietary energy balance toward skeletal muscle growth as  
19 opposed to fat deposition. Producers often feed beta-agonists to animals during the “finishing”  
20 stage of growth—the final period of weight gain before slaughter—to encourage a last-minute  
21 increase in muscle mass and overall carcass weight, increasing the profit margin for producers.

22 66. Available research, including from FDA’s own files<sup>2</sup>, shows that beta-agonists  
23 have substantial negative impacts on animal health, human health, and the environment.

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25  
26  
27 <sup>2</sup> From 2013 to 2019 Plaintiff ALDF received voluminous FDA records related to beta-agonists  
28 as the result of litigation under the Freedom of Information Act. FDA had these records in its  
possession at the time it approved Exuperior.

1           67.     Because beta-receptors are spread widely throughout the body as part of the  
2 sympathetic nervous system, a number of physiological side effects can manifest when these  
3 drugs are administered to animals.

4           68.     Beta-agonists induce increased heartbeat, relaxation of blood vessels and muscle,  
5 and contraction of cardiac tissue. FDA scientists have found that beta-agonists are linked to  
6 cardiomyopathy in cows, a disease of the heart that makes it harder for the heart to pump blood  
7 to the rest of the body, and other “adverse effects” on the heart. FDA is also aware that  
8 beta-agonists are linked to fatal respiratory distress in cows, which often occurs in conjunction  
9 with heat stress, overheating, or dust inhalation due to dry conditions.

10          69.     Scientists have also linked beta-agonists to a number of behavioral changes in  
11 animals that correspond to the physiological effects of the drug, including an increase in  
12 aggressiveness and a variety of adverse drug effects including hyperactivity, trembling, hoof  
13 loss, lameness, broken limbs, inability to walk, and fatigued cattle syndrome. These conditions  
14 make animals more difficult to handle, increasing the incidence of violence towards animals by  
15 handlers at feedlots and slaughterhouses, while also increasing the potential for handlers to be  
16 injured.

17          70.     Because Experior negatively influences animal behavior, it corresponds to an  
18 increased risk to humans who work with them. The beta-agonist Zilpaterol, for example, was  
19 voluntarily withdrawn by its drug sponsor, Merck, because slaughterhouses throughout the  
20 United States reported concerns about non-ambulatory, slow, and difficult-to-move cows, and  
21 cows with severely deteriorated hooves.

22          71.     FDA’s own files contain reports of adverse reactions to beta-agonists in workers  
23 and producers in the animal agriculture industry, as well as reports of beta-agonist residues in  
24 meat harming consumers. FDA has received numerous complaints from workers and consumers  
25 who experienced nausea, dizziness, respiratory issues, and other serious medical conditions  
26 requiring treatment and hospitalization, all after either being directly exposed to or consuming  
27 meat from animals fed beta-agonists.

1           72.     FDA’s files also contain acknowledgements from its own scientists that humans  
2 with compromised cardiovascular systems react adversely to beta-agonists, and in fact FDA  
3 scientists encouraged beta-agonist drug sponsors to investigate cardiac issues in further beta-  
4 agonist studies after tremors were seen in a pilot study. FDA scientists have also stated that beta-  
5 agonists’ “[e]ffects are not desirable for consumers of food containing residues of the drug.”

6           73.     Indeed, beta-agonists are banned or restricted in many other countries because of  
7 human safety concerns. All European Union members, China, Japan, South Korea, and Russia  
8 are some of the 168 countries that prohibit or restrict ractopamine, a popular beta-agonist, in pig  
9 production. The European Food Safety Authority panel that banned the drug based its decision in  
10 part on the fact that its data could not support a conclusion that the drug is safe.

11           74.     Beta-agonists also harm the environment. Animals excrete approximately 95% of  
12 the beta-agonist ractopamine that they ingest in the first three days after consumption, which  
13 then contaminates ground and surface waters when manure lagoons leak or land-applied manure  
14 runs off the land into waterways. Uneaten medicated animal feed can also be buried on the  
15 feedlot, further leaching the drugs into the environment. These discharges degrade water quality  
16 both for recreation and drinking water. This is significant with respect to Experiol, specifically:  
17 with a half-life of 723 days, it persists in the environment long after it is excreted. FDA’s  
18 approval of Experiol will add substantially to the cumulative amount of beta-agonists in the  
19 environment, thereby compounding their cumulative environmental effects.

20           75.     Finally, because the use of  $\beta$ -AAs in animals increases the likelihood that they  
21 will suffer from conditions that cause them to collapse before slaughter, there are increased food  
22 safety risks with consuming products derived from them. Cows raised or finished in feedlots  
23 already suffer from stress due to their living conditions or physical abuse. Stress depresses the  
24 immune system, making animals more susceptible to pathogens, and increases animals’  
25 susceptibility to and shedding of zoonotic bacteria such as *salmonella*. “Downer” animals who  
26 collapse into the dirt are further exposed to pathogens on the ground, which they then carry into  
27 the slaughterhouse. These additional contamination pathways expose consumers to increased  
28 health risks.

1 Beta-Agonist Combinations: Monensin & Tylosin

2 76. Monensin is a polyether carboxylic ionophore antibiotic widely used in ruminant  
3 animal feed, including cows raised for food.

4 77. FDA approved monensin in 1970. *See* NADA 38-878, 35 Fed. Reg. 7734 (May  
5 20, 1970).

6 78. Monensin is used for the treatment of coccidiosis in several animals, including  
7 cows raised for food. Monensin is also used to control ketosis and bloat and is used as a growth  
8 promoter. Monensin can be used as a growth promoter feed additive in cows raised for food  
9 because it is not used in human medicine and was therefore not classified as a critically  
10 important antibiotic for humans by the World Health Organization (“WHO”).

11 79. Researchers have shown that cows fed monensin excrete more than 50% of the  
12 drug into the environment through feces. Studies have frequently detected this excreted  
13 monensin in CAFO wastewater and groundwater near CAFOs and feedlots.

14 80. In 2006, the European Food Safety Authority explained that under typical dosages  
15 and conditions, monensin poses a risk to soil organisms. Even in low doses monensin has toxic  
16 effects on soil organisms.

17 81. Non-target animals are at a significant risk—including risk of death—from  
18 exposure to small doses of monensin.

19 82. Tylosin is an antibiotic and a bacteriostatic feed additive used in veterinary  
20 medicine to treat liver abscesses in cows raised for food.

21 83. FDA first approved tylosin for use as a veterinary drug in 1961. *See* NADA 012-  
22 491, 26 Fed. Reg. 4369 (May 19, 1961).

23 84. Tylosin is also used in human medicine. WHO and FDA consider tylosin  
24 “critically important” to human medicine.

25 85. Tylosin was used historically as a growth promoter, but FDA now only allows its  
26 use for “disease prevention.” The line between growth promotion and disease prevention is  
27 blurred: producers can still use tylosin on a daily basis to prevent liver abscesses in cows raised  
28

1 for food. Up to a third of cows on feedlots—where cows raised for food are fattened for up to six  
2 months before slaughter—suffer from liver abscesses.

3 86. Studies have shown that when tylosin is used at CAFOs, it leads to the  
4 development of tylosin-resistant bacteria. Using tylosin fuels resistance to erythromycin, an  
5 antibiotic used to treat people with chest infections, ear infections, and sexually transmitted  
6 diseases.

7 87. The European Union banned the use of tylosin as a growth promotor in 1999,  
8 with additional restrictions preventing its long-term use, because of its potential to render its use  
9 as a human antibiotic ineffective.

10 88. Under FDA rules, tylosin can still be administered on a daily basis for months at a  
11 time.

12 89. Tylosin was approved before Congress enacted NEPA. Upon information and  
13 belief, FDA has not addressed the environmental impacts of tylosin when fed to cows in a  
14 publicly available NEPA document.

15 90. Tylosin is commonly found in surface water. For example, a 2002 survey of  
16 surface waters in the United States found tylosin in 13.5% of streams sampled. Tylosin's surface  
17 water half-life is approximately 200 days. In 2006, Applied and Environmental Microbiology  
18 concluded that "high levels of tylosin resistance persisted for years after usage" in soil. In 2004,  
19 the Journal of Occupational and Environmental Hygiene found tylosin-resistant bacteria in the  
20 soil and air near CAFOs.

### 21 Beef Production in the United States

22 91. Cows are raised for beef in all 50 states. There are 913,246 cow and calf  
23 operations in the United States that raise 94.8 million cows each year, 31.8 million of whom are  
24 raised exclusively for beef.<sup>3</sup>

25 92. While the natural diet for cows is made up of forage (pasture, silage, hay), many  
26 cows are "finished" in feedlots on grain as a cost-effective way to increase animal weight, to

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27 <sup>3</sup> National Cattleman's Beef Association, Industry Statistics,  
28 <https://www.ncba.org/beefindustrystatistics.aspx> (last visited Sept. 29, 2020).

1 save time, and reduce total feed. Though the natural lifespan of a cow is 20 years, cows raised  
2 for beef are slaughtered at the age of 2 or 3.

3 93. Feedlots are a type of CAFO, which are characterized by high concentrations of  
4 animals who are confined in a manner that maximizes efficiency at the expense of animal health  
5 and well-being. These operations, which have become pervasive throughout the United States,  
6 harm water quality and quantity, endangered species, the confined animals themselves,  
7 community health, and other aspects of the human environment.

8 94. These harms outweigh any alleged benefit of increased production; CAFOs are  
9 simply not a viable or sustainable way to raise animals used as food.

10 95. Scientific research and government agency studies confirm the varied and  
11 disastrous impacts of CAFOs.

12 96. CAFOs are one of the largest sources of water pollution in the country.

13 97. The U.S. Environmental Protection Agency (“EPA”) has found that  
14 “[a]gricultural operations, including CAFOs, now account for a significant share of the  
15 remaining water pollution problems in the United States.”<sup>4</sup> Indeed, agriculture “is the leading  
16 contributor of pollutants to identified water quality impairments in the Nation’s rivers and  
17 streams.”<sup>5</sup> Twenty-nine states have recently made similar findings, identifying animal feeding  
18 operations as contributors to water quality impairment in EPA’s 2009 National Water Quality  
19 Inventory. 76 Fed. Reg. 65431, 65434 (Oct. 21, 2011).

20 98. Confined animals used for food in the United States produce roughly 500 million  
21 tons of manure per year, more than sixty-five times the mass of human biosolids treated by  
22 publicly owned treatment works. A single cow raised for beef is estimated to produce about 100  
23 times the waste of a single human; a feedlot raising just 1000 cows for beef thus produces as  
24 much waste as a city of 100,000 humans.

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26 <sup>4</sup> National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation  
27 Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs), 68 Fed. Reg.  
7176, 7181 (Feb. 12, 2003).

28 <sup>5</sup> *Id.*

1           99. Unlike concentrated human waste, which is handled by wastewater treatment  
2 plants that decompose and disinfect the waste to reduce its threat to water quality, CAFOs  
3 generally transfer animal waste into huge pits or basins, where they hold the manure until  
4 spreading it onto fields without much, if any, prior treatment.

5           100. The drugs excreted in animal waste are not treated or removed before the manure  
6 enters the environment.

7           101. CAFOs operate, and thus produce waste, throughout the year. Because crops do  
8 not grow throughout the year in many regions where CAFOs are prevalent, and waste applied to  
9 the ground when crops are not growing increases the risk of runoff, CAFOs must store waste for  
10 long periods of time and sometimes apply waste to fields even when the risk of runoff is high.  
11 Unlined or inadequately lined manure storage lagoons can contaminate communities' well water  
12 if the manure leaks through the soil into aquifers below.

13           102. When manure from these massive stockpiles is eventually applied to the ground  
14 or crops, it is usually sprayed or otherwise disposed of onto land without barriers between fields  
15 and waterways. Runoff, drainage, or percolation from land application of manure can  
16 contaminate surface waters with the pharmaceuticals administered to the animals, threatening the  
17 health of the aquatic ecosystem and members of the public who swim or recreate in the  
18 waterways. CAFOs can also affect groundwater quality by increasing salinity and contributing  
19 contaminants including pharmaceuticals. Thus, the CAFO system of manure disposal  
20 contaminates surface and ground waters used for drinking and recreation, and by imperiled  
21 species.

22           103. Nitrate contamination from cow manure can also cause downstream communities  
23 to bear significant costs to treat municipal drinking water. *See Bd. of Water Works Trustees of*  
24 *City of Des Moines, Iowa v. Sac County Bd. of Supervisors*, 890 N.W.2d 50, 54 (Iowa 2017)  
25 (stating that the Des Moines Water Works spends approximately \$4,000-\$7,000 per day to treat  
26 water contaminated by agricultural nitrate pollution, and that the Water Works will need to  
27 invest \$260 million to design and construct a larger treatment facility to ensure that water  
28 remains safe for human consumption).

1           104. Further, when manure pollutes surface water during winter and spring months, the  
2 contamination contributes to the creation and expansion of toxic blue-green algae blooms during  
3 the summer, which also impact public water supplies. For example, in 2014, a blue-green algae  
4 bloom caused the City of Toledo, Ohio to order its residents not to use public water for drinking,  
5 cooking or bathing.<sup>6</sup> Surface water pollution from CAFO waste has also led to algae blooms  
6 linked to major fish die-offs, significant decline of underwater plants, and odors and bacterial  
7 contamination that deter people from recreating on rivers, lakes, and other watercourses.  
8 Contaminated groundwater can also move laterally and enter rivers and streams to contaminate  
9 those surface waters.

10           105. The concentration of animals at CAFOs also produces air pollutants, including  
11 ammonia that Exporior purports to reduce. However, reducing ammonia emissions while  
12 confining the same or greater numbers of cows in CAFOs will do nothing to alleviate the overall  
13 air impacts of CAFOs because CAFOs emit a variety of air pollutants, including hydrogen  
14 sulfide, methane, nitrous oxide, volatile organic compounds, and particulate matter. They also  
15 emit pathogens—including those that carry antimicrobial resistance—and particles of bedding,  
16 manure, and other allergens. The number of animals at a CAFO is generally proportional to the  
17 air pollution it emits.

18           106. The U.S. Centers for Disease Control and Prevention consider airborne emissions  
19 from CAFOs to “constitute a public health problem.” Air emissions can cause serious and life-  
20 threatening health problems, and even death. The health problems include respiratory illnesses,  
21 irritation to the eyes, nose, and throat, anxiety and depression, memory loss, and heart disease.  
22 The effects are amplified in vulnerable populations like children and the elderly.

23           107. Hydrogen sulfide, for example, is a flammable, poisonous asphyxiant that  
24 produces an odor similar to rotten eggs. Hydrogen sulfide can cause difficulty breathing, loss of  
25 consciousness, shock, pulmonary edema, coma, brain damage, and death. Survivors of hydrogen

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26 <sup>6</sup> Carolyn L. McCarthy et al., Community Needs Assessment After Microcystin Toxin  
27 Contamination of a Municipal Water Supply – Lucas County, Ohio, September 2014, 65  
28 Morbidity & Mortality Weekly Report 925 (2016),  
<https://www.cdc.gov/mmwr/volumes/65/wr/mm6535a1.htm>.

1 sulfide poisoning commonly have neuropsychiatric defects, some of which can be permanent.  
2 Exposure to higher levels of hydrogen sulfide is immediately hazardous to human life and health.  
3 It can cause rapid loss of consciousness, then death, after one or two breaths. This has been  
4 referred to as the “slaughterhouse sledgehammer” effect. Even at low concentrations, hydrogen  
5 sulfide causes strong odors in areas surrounding CAFOs. The National Research Council has  
6 found hydrogen sulfide emissions from CAFOs to have a “significant” effect on the quality of  
7 human life.<sup>7</sup>

8         108. CAFOs and CAFO waste disposal also release the powerful greenhouse gases  
9 methane and nitrous oxide. Methane and nitrous oxide—two of the six greenhouse gases that  
10 “together constitute the root cause” of climate change and its “resulting impacts on public health  
11 and welfare,” 74 Fed. Reg. 66517 (Dec. 15, 2009)—are 20 and 300 times more powerful than  
12 carbon dioxide at trapping heat in the atmosphere over a 100-year period, respectively. Methane  
13 is produced by anaerobic decomposition of organic matter in biological systems and by the  
14 normal digestive process in ruminant animals. Nitrous oxide is typically a product of a microbial  
15 process occurring in soils and fertilizer via decomposition of livestock manure and urine. In  
16 2006, industrial animal agriculture was responsible for emitting almost nine million tons of  
17 methane in the United States alone. Increases in methane emissions correlate with the  
18 consolidation of the CAFO industry, with EPA reporting a 34% increase in methane emissions  
19 from manure management between 1990 and 2006.<sup>8</sup> Agricultural soil management activities,  
20 which include application of manure to the soil—particularly the application of liquid manure, as  
21 typically results from CAFOs’ use of manure lagoons—are the largest source of nitrous oxide  
22 emissions in the United States, producing approximately 72% of nitrous oxide emissions in  
23 2006.

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25 <sup>7</sup> Nat’l Research Council, *Air Emissions from Animal Feeding Operations: Current Knowledge, Future Needs* (2003).

26 <sup>8</sup> EPA, Report No. EPA-430-R-08-005, *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2006* (2008). That increase has rapidly grown in recent years, to a 65% increase between  
27 1990 and 2014. EPA, Report No. EPA-430-R-16-002, *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2014*, at 5-9 (2016).  
28

1           109. CAFOs are also a significant source of volatile organic compound (VOC)  
2 emissions. EPA defines VOCs as “any compound of carbon, excluding carbon monoxide, carbon  
3 dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which  
4 participates in atmospheric photochemical reactions.” 40 C.F.R. § 51.100(s). CAFOs emit VOCs  
5 through feed decomposition, fresh waste, enteric processes, and manure decomposition. CAFOs  
6 emit as many as 165 VOCs; of these, 24 are odorous chemicals and 21 are listed as Hazardous  
7 Air Pollutants under the Clean Air Act. 42 U.S.C. § 7412(b). CAFO-emitted Hazardous Air  
8 Pollutants include benzene, formaldehyde, tetrachloroethylene, methanol, toluene, and xylene.  
9 VOCs also react with other pollutants to form ground-level ozone, which causes a range of  
10 serious health effects. Some VOCs are toxic to the nervous system in both humans and animals.  
11 Studies examining neurobehavioral issues among humans living near CAFOs have found  
12 increased rates of depression, anger, fatigue, and confusion.<sup>9</sup> At least one study has shown VOCs  
13 can also cause serious problems in animals, including delayed weaning, higher stress levels, and  
14 reduced growth and appetite. Other effects include deteriorated muscles, organs, and respiratory  
15 functioning, and increased morbidity and mortality.

16           110. CAFOs also directly emit particulate matter, including particles of dry manure,  
17 bedding and feed materials, biological matter, and dusts. Indeed, CAFOs persistently cause  
18 National Ambient Air Quality Standards (NAAQS) exceedances because of their releases of  
19 VOCs and particulate matter.

20           111. Haze from CAFOs drastically reduces visibility, creates significant losses of  
21 public enjoyment of wildlife and wilderness areas, and harms tourism-dependent communities.

22           112. CAFOs routinely provide continuous doses of antibiotics to every animal  
23 confined within the facility, regardless of whether the animal is sick. Routine antibiotics are  
24 supposed to be primarily used to prevent sickness due to crowded, stressful confinement  
25 conditions.

26           113. Continuous, herd-wide and flock-wide use of antibiotics at CAFOs leads to the

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27 <sup>9</sup> E.g., S. Schiffman et al., *Quantification of Odors and Odorants from Swine Operations in*  
28 *North Carolina*, 1089 *Agric. & Forest Meteorology* 213 (2001).

1 development and spread of antibiotic-resistant bacteria; giving antibiotics to an entire group of  
2 animals at a facility in steady, low doses “strongly encourages” drug resistance, “especially when  
3 provided in feed or water, where they remain active and are widely dispersed.”<sup>10</sup> This resistance  
4 is then readily transmitted to surrounding bacteria.

5 114. Antimicrobial-resistant pathogens are capable of transferring to humans, and jump  
6 from manure, live animals, and animal carcasses at CAFOs to human populations via various  
7 environmental pathways. These pathways include through the air as dust, up from the soil into  
8 edible crops, into groundwater and surface waterways, and through the food chain during  
9 slaughter processes.

10 115. Scientific research and government findings tie antibiotic use in the raising of  
11 food-producing animals to increased antimicrobial resistance in bacterial populations in animals,  
12 the environment, and humans.

13 116. Indeed, a recent study of veterans in rural Iowa found that the risk of antibiotic-  
14 resistant *Staphylococcus aureus* (a bacteria species) was 88% higher among veterans living  
15 within one mile of high-density pig CAFOs.<sup>11</sup>

16 117. Upon human exposure, the resistant bacteria can colonize the human gut and  
17 cause illnesses resistant to clinically important antibiotics.

18 118. Antibiotic-resistant bacteria are such a significant threat that the United Nations  
19 General Assembly, acting for only the fourth time on a public health issue and the first time since  
20 the Ebola outbreak in 2014, declared resistance a “most urgent global risk.”<sup>12</sup> In 2014, President  
21 Obama issued an Executive Order declaring, “Combating antibiotic resistant bacteria is a

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22 <sup>10</sup> Stuart B. Levy, *Multidrug Resistance—A Sign of the Times*, 338 *New Eng. J. of Med.* 1376,  
23 1377 (1998); *see also* White House, National Action Plan for Combating Antibiotic-Resistant  
24 Bacteria 20 (2015).

25 <sup>11</sup> *See* M. Carrell et al., *Residential Proximity to Large Numbers of Swine in Feeding Operations*  
26 *is Associated with Increased Risk of Methicillin-Resistant Staphylococcus Aureus Colonization*  
*at Time of Hospital Admission in Rural Iowa Veterans*, 35 *Infection Control & Hosp. Control*  
*Epidemiology* 190 (2014).

27 <sup>12</sup> Press Release, United Nations, High-Level Meeting on Antimicrobial Resistance (Sept. 21,  
28 2016), [http://www.un.org/pga/71/2016/09/21/press-release-hl-meeting-onantimicrobial-](http://www.un.org/pga/71/2016/09/21/press-release-hl-meeting-onantimicrobial-resistance)  
[resistance](http://www.un.org/pga/71/2016/09/21/press-release-hl-meeting-onantimicrobial-resistance).

1 national security policy.” Exec. Order No. 13,676 (Sept. 18, 2014).

2 119. Along with antibiotic resistance, CAFOs put public health at risk through the  
3 spread of foodborne illnesses, which kill approximately 3,000 Americans, hospitalize 128,000,  
4 and sicken 48,000,000 every year. Foodborne *E. coli* in beef products are responsible for the  
5 most deaths each year. Stressed, injured, and non-ambulatory cows are more likely to contract  
6 bacterial infections, exposing workers and consumers to higher levels of dangerous bacteria.

7 120. Experior also enables CAFO operators to confine more cows per feedlot while  
8 touting lower ammonia emissions, thereby exacerbating the existing animal, public, and  
9 environmental health effects of the CAFO industry. And because CAFOs are shrouded in  
10 government-sanctioned secrecy, exempt from critical environmental reporting, and hidden  
11 behind claims of confidential business information, the public is all but helpless to prevent  
12 CAFOs’ harms while at the same time forced to support their very existence with their tax  
13 dollars.

#### 14 FDA’s Approval of Experior

15 121. On November 6, 2018, FDA announced on its website that it had approved  
16 Experior for use in cows raised for meat.<sup>13</sup> FDA did not publish the approval in the Federal  
17 Register, notwithstanding the Agency’s 30-day timeline by which to file a Petition for Stay of  
18 Action under 21 C.F.R. § 10.35.

19 122. Experior’s primary approved use is to reduce the ammonia gas released as a  
20 by-product of animal waste when fed under specific conditions to cows raised for beef on  
21 feedlots.

22 123. The approval of Experior is the first time FDA has approved a drug that purports  
23 to reduce gas emissions from an animal or its waste, increasing the need for thorough animal  
24 health and environmental studies about the potential effects of this drug.

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27 <sup>13</sup> FDA, FDA Approves Experior for Reduction of Ammonia Gas Released from Beef Cattle  
28 Waste (Nov. 6, 2018), <https://www.fda.gov/animal-veterinary/cvm-updates/fda-approves-experior-reduction-ammonia-gas-released-beef-cattle-waste>.

1           124. FDA’s November 6, 2018, approval was based on its narrow review of the drug  
2 sponsor’s application, EA, and supporting documents. FDA’s approval touted the potential  
3 environmental benefits of Experior—many of which are unsubstantiated in the corresponding  
4 approval documents—but cautioned that the studies on which FDA relied “did not measure  
5 ammonia gas emissions on a herd or farm scale and could not take into account other factors that  
6 may affect ammonia gas emissions, such as wind speed and direction, rainfall, weather, input  
7 from other nitrogen sources and manure management. Therefore, extrapolation to the herd, farm  
8 or larger scale could not be accurately or reliably predicted.”<sup>14</sup>

9           125. On December 6, 2019, Plaintiff ALDF submitted a timely Petition for Stay of  
10 Action under 21 C.F.R. § 10.35, requesting that FDA stay the approval of NADA 141-508 for  
11 Experior and the corresponding EA and FONSI.<sup>15</sup>

12           126. ALDF’s Petition outlined various deficiencies in FDA’s approval. For example,  
13 ALDF’s Petition illustrated that Experior has not been shown to be safe and effective in target  
14 animals, in violation of the FDCA, because Experior may have significant adverse consequences  
15 for animal health, including heat stress, lameness, and sudden death; and FDA admits that it  
16 could not make reliable predictions about the effectiveness of Experior at a herd, farm, or larger  
17 scale. ALDF further illustrated the potential for Experior to cause significant harm to the  
18 environment, underscoring FDA’s duty to conduct an EIS under NEPA. Finally, ALDF  
19 explained that FDA’s approval documents failed to consider any alternatives to the approval or  
20 to even mention threatened and endangered species, also violating NEPA. ALDF’s Petition  
21 showed that Experior is unsafe, or at best, that FDA lacked sufficient information to approve the  
22 drug. An approval that does not meet the FDCA’s and NEPA’s requirements causes irreparable  
23 harm to Plaintiffs because it legitimizes the use of a drug with known and unknown risks to  
24 target animal safety, human health, and the environment. ALDF requested that FDA stay the  
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27 <sup>14</sup> *Id.*

28 <sup>15</sup> See Animal Legal Defense Fund, Petition for Stay of Approval of Experior (Dec. 6, 2019),  
<https://www.regulations.gov/document?D=FDA-2018-P-4656-0001>.

1 approval of Experior unless and until these and other deficiencies are corrected, and the agency  
2 action is in compliance with the referenced statutes.

3 127. FDA did not publish notice of the Experior approval in the Federal Register until  
4 April 2, 2019, well after the 30-day deadline to petition for a stay of the action.

5 128. On May 20, 2019, FDA denied ALDF's Petition. FDA erroneously determined  
6 that the Petition did not meet the conditions set out in 21 C.F.R. § 10.35(e) requiring issuance of  
7 a stay. FDA further found that the Petition did not demonstrate that issuance of a stay under the  
8 Commissioner's discretion would be appropriate (i.e., in the public interest and in the interest of  
9 justice as set forth in 21 C.F.R. § 10.35).

10 129. FDA's response to ALDF's Petition was insufficient to justify either FDA's  
11 approval or its denial of the Petition. As explained below, the information provided by FDA in  
12 the Freedom of Information (FOI) Summary—the publicly-available summary of safety and  
13 effectiveness information that supports a new animal drug application—and reiterated by FDA in  
14 its response to ALDF did not contain sufficient data to refute or confirm the possible target  
15 animal safety impacts posed by Experior, could not confirm the effectiveness of Experior, and  
16 highlighted the myriad unknowns of how Experior will affect cows raised for beef when used  
17 under expected conditions.

18 130. FDA's response also underscored the potential environmental impacts associated  
19 with Experior. As explained below, FDA did not—either originally or in response to ALDF's  
20 Petition—adequately consider the effects that the presence of Experior in cow feces will have on  
21 the environment. FDA did not consider the cumulative environmental effects of the use of the  
22 drug over time or in combination with other drugs, and especially other beta-agonists that are  
23 already present in the environment. FDA conducted only the most cursory review of the impact  
24 Experior may have on invertebrates and aquatic species other than rainbow trout. FDA did not  
25 review the potential impacts of Experior on bees and pollinators. FDA thus lacked sufficient  
26 information to conclude that Experior would not significantly affect the environment or  
27 threatened and endangered species.

1           131. One day after denying ALDF's Petition, on May 21, 2019, FDA approved two  
2 Experior combination drugs, one with tylosin and one with monensin. FDA did not publish  
3 notice of these approvals in the Federal Register until October 7, 2019. These drug approvals  
4 tiered to FDA's approval of the original Experior formulation without any additional assessment  
5 of the cumulative impacts of these additional approvals, despite the fact that the additional  
6 approvals will increase the overall use of Experior in the United States.

7 Specific Deficiencies in FDA's Approval and Stay Denial

8 *Drug Safety in Target Animals*

9           132. The FDCA requires FDA to refuse any new animal drug application that has not  
10 been shown to be safe in target animals or where there is insufficient data to establish drug  
11 safety. The safety studies referenced in the FOI Summary fail to establish that the drug is safe for  
12 target animals.

13           133. Overall, the studies on which FDA relied contained inadequate experimental  
14 conditions to simulate feedlots and were based on small sample sizes. These studies are simply  
15 not able to accurately determine if and to what degree there will be an increase in serious health  
16 effects in cows, including fatal conditions that are known to be caused by  $\beta$ -AAs.

17           134. Most of the trials FDA reviewed were designed to measure ammonia and did not  
18 look adequately at biologically plausible and probable adverse events, including (but not limited  
19 to) lameness and overheating.

20           135. Where FDA did acknowledge the occurrence of adverse events, it dismissed them  
21 without explaining or addressing them.

22           136. For example,  $\beta$ 3-AAs including Experior are thermogenic, meaning they increase  
23 heat in the body through metabolic stimulation. The resulting increase in body temperature,  
24 especially in conjunction with the high environmental temperature that is common on feedlots,  
25 may cause or exacerbate serious or deadly adverse reactions in cows. Nevertheless, FDA failed  
26 to adequately consider Experior's contribution to heat stress. The studies cited in the FOI  
27 Summary failed to measure cortisol levels or other standard stress indicators, and the sample  
28 sizes in the trials cited in the FOI Summary are too small to be able to discern whether there

1 might be an increased risk of sudden death from overheating due to the drug. The animals  
2 subjected to the studies on Experior were not heat stressed and the studies failed to account for  
3 the likelihood of high temperatures on feedlots.

4 137. FDA's FOI Summary states that "[r]espiratory and digestive issues were the most  
5 common abnormal health effects noted." One of the first signs that a cow raised for beef is  
6 unhealthy is reduced appetite and growth. Studies indicate that animals fed Experior experienced  
7 poor appetite and other gastrointestinal issues (e.g. bloat), which repeatedly led to animals dying.  
8 Lameness was also widespread in the studies; animals fed Experior had a numerically higher  
9 incidence of lameness compared to the control group. Yet FDA dismissed these findings as  
10 non-significant.

11 138. When studied in humans, scientists found  $\beta$ 3-AAs in higher levels in human  
12 melanomas and other tumors.  $\beta$ 3-AAs are also known to increase blood pressure in humans. Yet  
13 the FOI documents do not address the effects and implications (if any) this may have on cows.

14 139. FDA further erroneously determined that Experior does not exhibit any  $\beta$ 2-AA  
15 activity. Experior does exhibit some  $\beta$ 2-AA activity.  $\beta$ 2-AAs are associated with many adverse  
16 events in cows and pigs, such as trembling, lameness, inability to rise or walk, reluctance to  
17 move, stiffness, hyperactivity, hoof disorders and total hoof deterioration, difficulty breathing,  
18 cardiomyopathy and other heart issues, collapse, and death. Research has shown the  $\beta$ 2-AA drug  
19 ractopamine, for example, can cause 75 to 90% higher mortality (unexpected deaths) and  
20 lameness in cows, especially cows in higher ambient temperatures. Cows fed zilpaterol, another  
21  $\beta$ 2-AA, also had significantly higher incidences of these health issues, which were sometimes  
22 fatal. FDA has this research in its own files. Yet FDA failed to acknowledge or address both the  
23 known impacts of beta-agonists that Experior is likely to replicate and the unknowns that  
24 distinguish Experior from other beta-agonists.

25 140. The precise mechanism by which Experior purportedly reduces ammonia gas was  
26 also not identified in the studies—and is unknown even to the drug sponsor. This is consistent  
27 with a general lack of information about the subtype of beta-agonists to which Experior belongs;  
28  $\beta$ 3-AAs have been the least studied of the  $\beta$ -AAs.  $\beta$ 3-AA drugs affect adipose, heart/vasculature,

1 urinary bladder, and ovary tissue, but without knowing exactly how the drug functions, the drug  
2 sponsor and FDA are necessarily unable to identify and address any side effects the drug may  
3 cause. For example, the FOI documents do not explain *how* nitrogen is used more efficiently  
4 with the use of Experior, and intimate that the reason is not known. This makes it impossible for  
5 FDA to conclude that the drug is safe.

6 141. FDA also failed to account for how  $\beta$ -AAs are processed by different animal  
7 breeds, to conclude that effects on cows either could or could not be extrapolated from studies on  
8 other animals. At least one study indicates that there is a significant difference in how various  
9 animals respond to  $\beta$ -AAs, indicating a need for further research on the effects of Experior on  
10 cows.

11 142. In so doing, FDA ignored evidence in its own files about the negative animal  
12 health effects of beta-agonists.

13 143. At best, it is unknown what Experior's effects on cows might be; at worst, it will  
14 have severe, unintended negative effects.

15 *Drug Effectiveness in Target Animals*

16 144. The FDCA requires FDA to refuse any new animal drug application that has not  
17 been shown to be effective in target animals.

18 145. The FOI Summary readily admits that reliable predictions of the effectiveness of  
19 the drug at a herd, farm, or larger scale "cannot be made."

20 146. The FOI Summary illustrates that ammonia gas emissions vary depending on the  
21 size of the animal, the quantity of feed consumed, and other factors.

22 147. The FOI Summary also illustrates that a certain amount of data manipulation was  
23 necessary to achieve the desired outcome on effectiveness. The studies on which FDA relied  
24 were all done on relatively small sample sizes, then only a post hoc Bonferroni correction—a  
25 multiple-comparison correction used when several dependent or independent statistical tests are  
26 being performed simultaneously—resulted in a statistically significant decrease in ammonia  
27 levels with increased dosage. Only by using p-values instead of Confidence Intervals and  
28 eliminating two "outlier" groups did the studies result in the reported decrease in ammonia.

1 148. In short, Experior has not been shown to be effective.

2 *Effects on the Environment*

3 149. Experior is purported to reduce ammonia emissions from cow manure. Urine and  
4 fecal material, individually, emit minimal amounts of ammonia; it is the physical process of  
5 combining urine and feces after deposition on a surface that results in ammonia volatilization  
6 (ammonia gas). Yet Experior itself will enter the environment through manure, and FDA fails to  
7 identify several known risks of environmental contamination due to CAFO manure management  
8 practices that will enable Experior to permeate the environment.

9 150. The EA states that Experior will only enter the environment through land  
10 application of manure and corresponding runoff and will not contaminate groundwater. It fails to  
11 consider that manure can be stored in unlined lagoons that are susceptible to leakage, overflow,  
12 or rupture, any of which could lead to groundwater and soil contamination. It also fails to  
13 account for uneaten medicated feed which could also contaminate groundwater and soil.

14 151. The EA further relies on severely underestimated numbers with regard to daily  
15 manure production but fails to explain the basis of such numbers beyond obliquely stating that  
16 the “[v]alue is consistent with values typically used in environmental risk assessments.”

17 152. The Experior FONSI also failed entirely to consider alternatives to the proposed  
18 action, as NEPA requires. FDA thus failed to acknowledge that it could have denied the  
19 application or placed strict conditions on Experior’s use to avoid the substantial environmental  
20 burden imposed by an additional, widespread approval of a new beta-agonist throughout the  
21 United States.

22 153. FDA’s denial of ALDF’s Petition also erroneously states that if more cows were  
23 to be confined and produce a higher volume of manure, it would result in lower concentrations of  
24 Experior in the environment. The concentration in the manure would be lower for each animal if  
25 total quantity of excreted drug is constant, but the total concentration in the environment will not  
26 necessarily be lower since this is dependent on the total number of animals given the drug, the  
27 density of animals in the environment, and manure management practices—not only on the  
28 concentration in the manure.

1           154. FDA also assigns any responsibility for poor manure management conditions to  
2 the EPA. However, FDA, not EPA, has a duty to analyze this eventuality before approving a new  
3 animal drug. Manure mismanagement, and environmental contamination from even “proper”  
4 manure management, is common; FDA failed to analyze this as part of its approval, relying  
5 improperly on EPA’s role in enforcing federal laws designed to protect navigable waters.  
6 Moreover, EPA notoriously underregulates the CAFO industry. As early as 1994, EPA  
7 acknowledged that agriculture is the leading contributor to water quality impairments, and that  
8 pollution associated with animal feeding operations degrades the quality of waters and threatens  
9 drinking water sources. In 2012, the EPA estimated that there may be a total of 18,540 animal  
10 confinement facilities that meet the federal Clean Water Act’s CAFO definition, 40 C.F.R.  
11 § 122.23(b)(2), but just 7,642 of those facilities maintained Clean Water Act permits. As of  
12 2018, only 6,597 were permitted.<sup>16</sup> Accordingly, the majority of CAFOs may be discharging  
13 manure contaminated with Experior and other animal drugs in open violation of state and federal  
14 law. FDA failed to consider this.

15           155. FDA further accepted the drug sponsor’s assertion that very little Experior would  
16 be excreted by cows unchanged and that there are no deleterious metabolites, despite this  
17 statement being largely unsubstantiated and not at all congruous with the excretion rates of other  
18 beta-agonists.

19           156. FDA also failed to consider the impacts of Experior on aquatic species and other  
20 threatened and endangered wildlife. The drug approval documents contain limited research on  
21 the effects of Experior on aquatic species, including invertebrates, except for one small study on  
22 rainbow trout, noted in the FOI Summary. They also fail to address that reduced growth and  
23 number of viable fish eggs and other deleterious effects have been reported with other  $\beta$ -AAs in  
24 water, or that there has been virtually no research done on the effects of  $\beta$ -AAs on bees or other  
25 pollinators.

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27 <sup>16</sup> EPA, NPDES CAFO Regulations Implementation Status Reports – National Summary,  
28 Endyear 2018, <https://www.epa.gov/npdes/npdes-cafo-regulations-implementation-status-reports>  
(last visited Sept. 29, 2020).

1 157. Finally, FDA failed to account for unknowns. As described above, the precise  
2 mechanism by which Experior purportedly reduces ammonia gas was not identified in the new  
3 drug approval application and is unknown even to the drug sponsor; the FOI documents do not  
4 explain *how* nitrogen is used more efficiently with the use of Experior, and intimate that the  
5 reason is not known. Without knowing exactly how the drug functions, the drug sponsor and  
6 FDA are necessarily unable to identify and address any environmental side effects the drug may  
7 cause, including any possible increase in other pollutants caused by or associated with the  
8 claimed reduction in ammonia.

9 158. In so doing, FDA ignored evidence in its own files about the negative  
10 environmental effects, and particularly cumulative effects, of beta-agonists.

### 11 **FIRST CLAIM FOR RELIEF**

#### 12 **FDA unlawfully denied Plaintiff ALDF's Petition**

13 1. Plaintiffs reallege and incorporate by reference all prior paragraphs, as though  
14 fully alleged herein.

15 2. FDA's regulations allow any interested person to submit an administrative request  
16 to stay an action. 21 C.F.R. § 10.35.

17 3. The Commissioner shall grant a stay in any proceeding if all of the following  
18 apply: (1) the petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not  
19 frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public  
20 policy grounds supporting a stay; and (4) the delay resulting from the stay is not outweighed by  
21 public health or other public interests. *Id.* § 10.35(e)(1).

22 4. A timely petition to stay exhausts administrative remedies. *Id.* § 10.45(c).

23 5. Plaintiff ALDF filed a timely Petition illustrating (1) that it would suffer  
24 irreparable harm by FDA's failure to stay the Experior approval pending further review; (2) that  
25 its petition was in good faith and not frivolous; (3) that ensuring target animal safety and  
26 effectiveness and compliance with environmental laws are sound public policy grounds that  
27 support a stay; and (4) that any delay is not outweighed by public health or other public interests.  
28

1 159. FDA erroneously denied ALDF's Petition.

2 160. In so doing, FDA acted in violation of § 706(2) of the APA because it "relied on  
3 factors which Congress has not intended it to consider, entirely failed to consider an important  
4 aspect of the problem, offered an explanation for its decision that runs counter to the evidence  
5 before the agency, or is so implausible that it could not be ascribed to a difference in view or the  
6 product of agency expertise." *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*,  
7 463 U.S. 29, 43 (1983).

8 6. FDA's denial of a petition to stay, and specifically ALDF's Petition, is final  
9 agency action subject to judicial review under the APA. *See* 5 U.S.C. § 704.

10 7. FDA's failure to comply with the FDCA and the APA harms Plaintiffs and their  
11 members' interests.

12 **SECOND CLAIM FOR RELIEF**

13 **FDA unlawfully approved Exuperior in violation of the FDCA and the APA**

14 8. Plaintiffs reallege and incorporate by reference all prior paragraphs, as though  
15 fully alleged herein.

16 9. The FDCA deems new animal drugs "unsafe" unless FDA has approved a new  
17 animal drug application for the drug and its use conforms to its labeling and the conditions of the  
18 approved application. 21 U.S.C. § 360b(a)(1).

19 10. The FDCA requires FDA to refuse any new animal drug application where it has  
20 not been shown to be both safe and effective. *Id.* § 360b(b).

21 11. FDA approved Exuperior without showing it to be either safe or effective.

22 12. FDA's 2018 approval of Exuperior is a final agency action subject to judicial  
23 review under the APA. *See* 5 U.S.C. § 704. ALDF's timely Petition exhausted its administrative  
24 remedies. *See* 21 C.F.R. § 10.45(c).

25 13. In approving Exuperior, FDA violated § 706(2) of the APA because it "relied on  
26 factors which Congress has not intended it to consider, entirely failed to consider an important  
27 aspect of the problem, offered an explanation for its decision that runs counter to the evidence  
28 before the agency, or is so implausible that it could not be ascribed to a difference in view or the

1 product of agency expertise.” *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*,  
2 463 U.S. 29, 43 (1983).

3 14. Its decision to approve Experior even though the new animal drug application  
4 failed to meet the requirements of the FDCA also exceeded its statutory authority. 5 U.S.C.  
5 § 706(2).

6 15. FDA’s failure to comply with the FDCA and the APA harms Plaintiffs and their  
7 members’ interests.

### 8 **THIRD CLAIM FOR RELIEF**

#### 9 **FDA unlawfully approved Experior in violation of NEPA and the APA**

10 16. Plaintiffs reallege and incorporate by reference all prior paragraphs, as though  
11 fully alleged herein.

12 17. FDA’s approval of Experior is a final, major federal action that requires  
13 compliance with NEPA and is subject to judicial review under the APA. 5 U.S.C. § 704.

14 18. ALDF’s timely petition to stay FDA approval of Experior exhausts administrative  
15 remedies. *See* 21 C.F.R. § 10.45(c).

16 19. NEPA requires agencies to explain why a proposed action will not have a  
17 significant effect on the human environment. 42 U.S.C. § 4332; 40 C.F.R. § 1508.27 (2018).

18 20. FDA did not take the requisite “hard look” at the environmental impacts of its  
19 decision to approve Experior, failed to consider the potential national human health and safety  
20 impacts of its action despite significant risk and concern of such impacts, and never considered  
21 any of the factors required by agencies to determine the intensity of a proposed action’s  
22 environmental impacts.

23 21. NEPA requires agencies to “rigorously explore and objectively evaluate” any  
24 reasonable alternatives to the proposed action. *Id.* § 1502.14(a) (2018); 42 U.S.C. § 4332(2)(E).  
25 The Experior FONSI failed entirely to consider alternatives to the proposed action.

26 22. CEQ regulations also require an agency to consider the direct, indirect, and  
27 cumulative impacts of a proposed action’s impact on the environment. *Id.* § 1508.8 (2018). FDA  
28 failed entirely to consider cumulative impacts.



1 DATED: September 29, 2020 in San Francisco, California.

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Signed: /s/  
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