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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.

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Animal Legal Defense Fund ("ALDF"), Food & Water Watch ("FWW"), and Food Animal Concerns Trust ("FACT") challenge the United States Food and Drug Administration's ("FDA" or "the Agency") approval of and subsequent denial of a petition to stay approval of Experior™ (lubabegron Type A medicated article), a beta 3-adrenergic agonist/antagonist ("β3-AA") manufactured by Elanco US, Inc., that allegedly results in less ammonia gas released from the waste produced by cows raised for beef.

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

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

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

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

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

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

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

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

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

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

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

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

14. By failing to meet the standards required of it by either statute when it approved Experior and its progeny, FDA violated the FDCA, NEPA, the Administrative Procedure Act ("APA"), and its own regulations. This Court should vacate FDA's unlawful approval of Experior and remand this matter to FDA with instructions to carry out any approval in accordance with federal law.

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) because Plaintiff Animal Legal Defense Fund resides in the Northern District of California.

17. Plaintiff Animal Legal Defense Fund resides in the county of Sonoma. 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 235,000 members and supporters throughout the United States, many of whom live near, recreate near, and closely monitor CAFOs in their communities.

20. Plaintiff **Food & Water Watch** ("FWW") is a national, nonprofit membership organization that mobilizes regular people to build political power to move bold and uncompromised solutions to the most pressing food, water, and climate problems of our

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