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

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| CENTER FOR FOOD SAFETY, CENTER FOR BIOLOGICAL DIVERSITY, and SIERRA CLUB,<br><br>*Plaintiffs*,<br><br>v.<br><br>MARGARET A. HAMBURG, COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, and UNITED STATES FOOD AND DRUG ADMINISTRATION,<br><br>*Defendants*. | Case No. 3:14-cv-4932<br><br>**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** |

## INTRODUCTION

1. This is an action for declaratory and injunctive relief. Plaintiffs Center for Food Safety, Center for Biological Diversity, and Sierra Club challenge the United States Food and Drug Administration (FDA or the Agency)'s approval of eleven new applications of animal drugs containing ractopamine hydrochloride (ractopamine)—a controversial feed additive banned or restricted in dozens of nations, including all of the European Union and China—without conducting the environmental analysis required by the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-70. This suit specifically challenges eleven new and combined animal drugs containing ractopamine that FDA approved for use in more than an estimated one billion pigs, turkeys, and cows from 2008 to 2014. These include new combinations of ractopamine with controversial antibiotics like tylosin, which is in the same drug class as erythromycin, an important human antibiotic; monensin; and the growth-promoting steroid hormone melengestrol acetate (melengestrol).

2. Plaintiffs are requesting immediate review because the use of ractopamine in food-producing animals poses a risk to humans, animals, and the environment. Ractopamine is a nontherapeutic beta-agonist pharmaceutical that is fed to cattle, pigs, and turkeys to boost growth rates. Scientists have linked ractopamine exposure to numerous adverse health events in humans and animals, including abnormal heartbeat, aggression, hyperactivity, collapse, and even death. Ractopamine is used in areas throughout the country that are habitat for threatened and endangered plants and wildlife, despite its manufacturer's admission that the drug is toxic to plants and aquatic invertebrates.

3. FDA approved Topmax, a ractopamine-based animal drug for turkeys, in 2008, and reviewed only a cursory Environmental Assessment (EA) prepared by the drug company applicant in 2001. That EA focused narrowly on the predicted impacts of the limited use of ractopamine alone, on a small segment of the overall market for turkeys, and made no meaningful attempt to address the cumulative impacts of the current use of ractopamine and ractopamine-based combination drugs in the vast majority of pigs, cattle, and turkeys slaughtered for food in the United States. FDA issued a one-page Finding of No Significant Impact (FONSI),

which did not consider any alternatives, did not involve the public in the review process, and did not explain why an EIS was not required by law. FDA did not address the significant changes in the industry that occurred between the time the applicant prepared the EA and when it approved the drug. For instance, the 2001 EA used 1998 statistics for national turkey populations—ten years out of date at the time of approval—and did not account for the growing U.S. pig population, also being fed ractopamine, which increased by nearly ten million animals between 2001 and 2008.

4. For ten of the ractopamine-based New Animal Drug Applications challenged in this case, the Agency conducted no NEPA analysis at all. FDA acknowledged that NEPA applied to these supplemental New Animal Drug Applications, but invoked "categorical exclusions" to evade NEPA analysis entirely.

5. Despite the far-reaching impacts of FDA's approvals of the challenged ractopamine-based combination drugs on uncounted consumers, billions of animals, millions of acres of habitat, and thousands of farm workers, FDA has never prepared an Environmental Impact Statement (EIS) or even an EA of the cumulative human health, worker safety risks, and adverse environmental impacts of the widespread discharge of millions of pounds of these combination drugs into the environment each year. FDA exhibits a pattern and practice of approving increased use and different drug combinations for ractopamine without any public disclosure or analysis.

6. FDA violated NEPA and the Administrative Procedure Act (APA). This Court should set aside FDA's unlawful approvals of ractopamine-based animal drugs, and remand this matter to FDA with instructions to carry out future approvals in accordance with NEPA.

## JURISDICTION AND VENUE

7. This Court has jurisdiction over this action under 28 U.S.C. § 1331 (federal question) and 5 U.S.C. § 702. (APA).

8. Venue is proper in this Court under 28 U.S.C. § 1391(e) because Plaintiff Sierra Club resides in the Northern District of California.

9. Plaintiff Sierra Club resides in the county of San Francisco. Accordingly, assignment to the San Francisco Division or the Oakland Division is proper pursuant to Civil Local Rules 3-2(c) and (d).

10. 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**

11. Plaintiff Center for Food Safety (CFS) is a public interest organization with more than 500,000 members, and offices in San Francisco, California; Portland, Oregon; Honolulu, Hawai'i; and Washington, District of Columbia. CFS's mission is to protect the public's right to know how their food is produced. CFS is dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies, such as animal factories or concentrated animal feeding operations (CAFOs), and instead promoting sustainable agriculture. CFS was established for the purpose of protecting the public by challenging harmful food production technologies and promoting sustainable alternatives. CFS works to inform, educate, and counsel its members and the public on the harm done to human health, animal welfare, and the environment by industrial agriculture.

12. CFS regularly comments on agency actions, EAs, and EISs. CFS utilizes legal petitions for rulemaking, public education, grassroots organizing, media outreach, and when necessary, litigation, to promote transparency and accountability in the factory farm and industrial agriculture industry. CFS has a procedural interest in commenting on any NEPA documents concerning ractopamine-based animal drugs, and an organizational interest in ensuring that the environmental and human health risks of animal drugs are fully analyzed.

13. CFS members have an aesthetic interest in keeping the areas where they recreate, hike, watch birds, swim, and live free of manure contaminated with ractopamine, antibiotics, and steroids. Use of ractopamine, antibiotics, and steroids compromises native ecosystems and wildlife, and injures the aesthetic and recreational interests of those who seek to protect and

maintain biodiversity. Because of FDA's unlawful approvals, CFS members are at greater risk of suffering health effects from animal drug use.

14. Plaintiff Center for Biological Diversity (CBD) is a nonprofit, public interest corporation with approximately 800,000 members and online activists, and offices in San Francisco, California; Washington, District of Columbia, and elsewhere in the United States. CBD and its members are dedicated to protecting diverse native species and habitats through science, policy, education, and environmental law.

15. Members of CBD have an aesthetic interest in keeping the areas where they hike, watch birds, swim, and live free of manure contaminated with ractopamine, antibiotics, and steroids. CBD members reside or own property and use waterways and environments throughout the United States that are impacted by pollution from animal feeding operations.

16. Plaintiff Sierra Club is a national nonprofit organization of approximately 600,000 members dedicated to exploring, enjoying, and protecting the wild places of the earth; to practicing and promoting the responsible use of the earth's ecosystems and resources; to educating and enlisting humanity to protect and restore the quality of the natural and human environment; and to using all lawful means to carry out these objectives. Sierra Club's concerns encompass the regulation of animal drugs and their environmental impacts. Sierra Club's particular interest in this case and the issues with which the case concerns stems from Sierra Club's goals to protect the health of the people of the earth and to maintain a healthy and diverse ecosystem through the use of sustainable methods of food production.

17. Sierra Club has a procedural interest in commenting on any NEPA documents concerning ractopamine-based animal drugs, and an organizational interest in ensuring that the environmental and human health risks of animal drugs are fully analyzed.

18. Sierra Club members have an aesthetic interest in keeping the areas where they hike, watch birds, swim, and live free of manure contaminated with ractopamine, antibiotics, and steroids. Sierra Club members who eat meat also have a consumer interest in knowing and avoiding any health and safety risks of drug-contaminated meat.

## STATUTORY AND REGULATORY FRAMEWORK

National Environmental Policy Act

19. NEPA is "our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a). NEPA emphasizes the importance of comprehensive environmental analysis and requires agencies make informed decisions by taking a "hard look" at potential environmental consequences before taking action. It also ensures that "environmental information is available to public officials and citizens before decisions are made and before actions are taken." *Id.* § 1500.1(b).

20. All "major Federal actions significantly affecting the quality of the human environment" require the preparation of a detailed EIS. 42 U.S.C. § 4332(2)(C). A threshold issue is whether a proposed project may "significantly affect" the environment.

21. Congress created the Council on Environmental Quality (CEQ) to promulgate regulations applicable to all federal agencies to promote and implement NEPA. *Id.* § 4342.

22. CEQ's regulations direct agencies to prepare an EA to determine whether the proposed action will have a significant impact on the environment and warrant the preparation of an EIS. 40 C.F.R. § 1508.9. An EA must provide sufficient evidence and analysis to allow an agency to determine whether it should prepare an EIS or a FONSI.

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

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

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

26. NEPA also imposes a continuing duty to supplement previous environmental documents. Agencies must supplement their environmental analysis documentation when "there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. § 1502.9(c)(1)(ii); 21 C.F.R. § 25.42(c).

Categorical Exclusions and Extraordinary Circumstances

27. The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301-399, and its accompanying regulations govern the use and approval of all new animal drugs, 21 U.S.C. § 360b. FDA's FFDCA regulations implement "NEPA in a manner that is consistent with FDA's authority under the [FFDCA] . . . ." 21 C.F.R. § 25.1.

28. FDA's regulations categorically exclude New Animal Drug Applications and supplemental New Animal Drug Applications from NEPA review if the action does not increase the use of the drug. *Id.* § 25.33(a).

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

Administrative Procedure Act

30. The APA allows any person adversely affected by agency action to seek judicial review, 5 U.S.C. § 702, and requires the court to "hold unlawful and set aside agency action, findings, and conclusions found to be [] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A).

## FACTS

Ractopamine

*Background on Ractopamine*

31. Ractopamine is a phenethanolamine beta-adrenoceptor agonist (beta agonist), a pharmacological agent that, among other metabolic effects, shifts dietary energy balance toward skeletal muscle growth as opposed to fat deposition.

32. Because beta-receptors are spread widely throughout the body as part of the sympathetic nervous system, a number of other physiological side effects can manifest when the drug is administered to farm animals. Studies have shown that ractopamine speeds up an animal's heart rate as a consequence of elevated catecholamine stress hormones.

33. Scientists have linked ractopamine to a number of behavioral changes in animals, including an increase in aggressiveness, and a variety of adverse drug effects including hyperactivity, trembling, broken limbs, inability to walk, difficulty breathing, and even death.

34. In 2002, three years after FDA first approved ractopamine, the FDA Center for Veterinary Medicine Office of Surveillance and Compliance sent Elanco—the ractopamine manufacturer—a letter accusing the company of withholding information about the drug's "adverse animal drug experiences" and "safety and effectiveness." The letter noted the "unusual failure" of the drug "to exhibit its expected pharmacological activities." FDA also required Elanco to add warning labels that read "Ractopamine may increase the number of injured and/or fatigued pigs during marketing." 21 C.F.R. § 558.500(d)(2)(ii); *see also* 67 Fed. Reg. 47,691 (July 22, 2002).

35. Elanco markets ractopamine as a feed additive to induce faster growth and leaner meat in pigs, cattle, and turkeys. The drug causes more, and faster, muscle mass accumulation than would otherwise occur in animals to which it is fed. This allows the pork, beef, and turkey industries to raise more animals in the same period of time, thus the drug's use inherently encourages and results in increased usage over time.

36. FDA approved ractopamine for use in pigs in 1999 under the brand name Paylean, and subsequently approved ractopamine for cattle and turkeys. Since its initial approval, ractopamine use has increased significantly in the pork, beef, and turkey industries.

37. Elanco originally predicted ractopamine would achieve "[a]n optimistic market penetration of 30%" of American pigs. Today, approximately 60% to 80% of pigs raised in the United States are fed ractopamine, along with undisclosed numbers of cattle and turkeys.

38. Since ractopamine was approved for use in pigs in 1999 the U.S. pig population has increased by more than ten million animals.

39. Dozens of nations, including all European Union members, China, and Russia, prohibit or restrict ractopamine because of human safety concerns. The European Food Safety Authority panel studying the drug explained their decision in part because their data could not support the safety of ractopamine.

40. FDA based its original safety approval for ractopamine on just one human health study—a study of six young, healthy men, one of whom dropped out because his heart began racing and pounding abnormally.

41. FDA does not require any withdrawal period for ractopamine before slaughter. A 2006 scientific study concluded "there is a possibility that adulteration of feed with ractopamine could result in residues in animal tissues and lead to human poisoning." A 2013 Consumer Reports test of 240 U.S. pork products found that about one in five tested positive for ractopamine residues.

*Ractopamine's Food Safety Risks*

42. The connection between foodborne illness and the conditions in animal factories is well-documented. Virtually all meat consumed in the United States comes from large CAFOs. Injuries to animals raised for food have a direct impact on the safety of our food system.

43. Each year, foodborne illnesses kill 3000 Americans. Foodborne *Listeria* in poultry and *E. coli* in beef are responsible for the most deaths each year. Foodborne *Salmonella* hospitalizes thousands of people each year. Data from the United States Department of Agriculture places the total cost of foodborne illnesses at over 15.5 billion dollars annually.

44. Animals that suffer adverse health events are more likely to contract bacterial infections, exposing workers and consumers to higher levels of dangerous bacteria.

45. Ractopamine is linked to more adverse events in pigs than any other animal drug on the market, with 218,116 reported adverse events in pigs through March, 2011 (FDA has clarified that 160,917 of those events were related to morbidity, a more recent data set increased that number to 170,400). The most common adverse events associated with ractopamine are trembling, lameness, inability to rise or walk, reluctance to move, stiffness, hyperactivity, hoof disorder, difficulty breathing, collapse, and death.

46. Specific examples of these adverse events include:

- "Producer reported that he plans to stop using ractopamine because he has had 10 to 12 deads [sic] on trucks. Previously had 1-2 deads [sic] per week on average."
- "Pigs in a research barn squeal when they take steps, as if in pain. Most noticeable when loading for shipping. Pigs would vocalize and refuse to leave the pen despite proper handling procedures. The animals were described as seeming painful, as if cramping. This is an ongoing issue at this site with ractopamine fed pigs."
- "The adverse events [in a 2009 study] involving Paylean 9 included 2 deaths, 2 observed for lameness and one chewed rectum."
- "17 finishing hogs found dead 8/27/02; 8 other pigs were dyspneic [difficulty breathing], weak and slow to move. [One] was euthanized and necropsied, one of the pigs found dead was also necropsied: small amount of bleeding kidney."
- Pigs were reluctant to unload from truck, and required "an excessive amount of prodding and hot shot use . . . they seemed to have no energy."

47. Pigs fed ractopamine are also more susceptible to stress. Kansas State University researchers found that pigs fed ractopamine had increased concentrations of the stress hormone cortisol when handled compared to pigs not fed ractopamine.

48. Ractopamine also increases the circulating concentrations of the stress hormone norepinephrine in pigs. Norepinephrine increases the growth and production of virulence factors in foodborne pathogens. An increase in norepinephrine levels in pigs may significantly increase the presence of *E. coli* and *Salmonella*.

49. Ractopamine may itself significantly increase bacteria levels in treated animals. In one study, researchers applied a dose of ractopamine approximating gut concentrations in feedlot steers and finishing pigs to bacteria in vitro. The researchers found that the addition of ractopamine significantly increased the growth rate for *Salmonella choleraesuis*.

50. Pigs fed ractopamine are more likely to collapse before slaughter than other pigs. Non-ambulatory pigs are more likely to require handling not just at farms, but also in transit to, and at slaughter facilities—exposing workers to safety risks. Collapsed pigs are also significantly more likely to contract *E. coli*, *Salmonella*, and *Campylobacter* in transport and at slaughter.

51. Non-ambulatory pigs are on average held much longer at slaughter facilities than those that can walk. Much of the pre-slaughter *Salmonella enterica* infection in pigs occurs immediately before slaughter during this period in contaminated holding pens.

52. Ractopamine causes pigs to suffer more frequently from hoof lesions. Researchers in a 2009 study found more cracks, bruises, and erosions on the feet of ractopamine-fed pigs at the time of slaughter. Hoof lesions can lead animals to collapse at slaughter.

53. Ractopamine makes pigs more aggressive. Pigs fed ractopamine are more likely to attack, bite, and injure other pigs. Pig aggression causes a significant amount of injury for workers in the pork industry.

54. Pigs fed ractopamine are more likely to induce human handlers to use more harsh methods to move them for routine procedures. A 2003 study found that pigs fed ractopamine needed 52% more pats, slaps, and pushes from the handler to enter the weighing scales. Workers are most vulnerable to injury when pigs are difficult to handle, when they do not exit their pens voluntarily, and take longer and require more force to move them.

55. Upon information and belief, FDA has never adequately assessed the food safety impact, or public health and safety effects of ractopamine in a publicly available NEPA document as required under title 40 section 1508.27(b)(2) of the Code of Federal Regulations.

*Ractopamine's Impacts on the Environment*

56. Ractopamine enters the environment mainly through livestock manure. Confined food animals in the United States produce roughly 500 million tons of manure per year, more than sixty-five times the mass of human biosolids generated by publicly owned treatment works.

57. Almost all ractopamine fed to cattle, pigs, and turkey is excreted into their manure. Much of this manure is generated at CAFOs. CAFOs lack sufficient land to absorb the manure produced by the animals they confine. Instead, this manure is pumped into open-air lagoons, or disposed—without treatment to remove ractopamine—through application to nearby lands or through in-ground injection.

58. These storage and disposal methods can, and often do, contaminate groundwater, streams, rivers, and other surface waters. Active residues, such as ractopamine and its combination drugs, present a significant adverse impact on these aquatic environments.

59. Elanco acknowledges the risk of impacting the chemical composition of water bodies by "potential leaching into the soil and groundwater from confinement areas . . . and runoff from land fertilized with manure from treated animals." Elanco also acknowledges ractopamine may enter waterways through runoff from cropland soils and potentially alter the chemical composition of those waterways. Nonetheless, Elanco has apparently never conducted a field study of ractopamine's impact on the chemical composition of waterways.

60. As of 2012, the United States Environmental Protection Agency (EPA) has estimated that there may be a total of 18,540 animal confinement facilities that meet the Clean Water Act's CAFO definition, 40 C.F.R. § 122.23(b)(2), but just 7642 of those facilities maintain Clean Water Act permits. Accordingly, the majority of CAFOs may be discharging manure contaminated with ractopamine and other animal drugs in open violation of state and federal law.

61. EPA acknowledges that "agriculture is the leading contributor to water quality impairments," and that "[p]ollution associated with [animal feeding operations] degrades the quality of waters [and] threatens drinking water sources."

62. Upon information and belief, FDA has never adequately assessed the unique characteristics of the geographic area where ractopamine is and may be used in a publically available NEPA document as required under title 40, section 1508.27(b)(3) of the Code of Federal Regulations.

63. Upon information and belief, FDA has never adequately assessed the effects of ractopamine that threaten to violate environmental laws in a publically available NEPA document as required under title 40, section 1508.27(b)(10) of the Code of Federal Regulations.

64. Upon information and belief, FDA has never adequately assessed the impacts and potential for serious harm to the environment stemming from ractopamine in a publically available NEPA document as required under title 21, section 25.21(a), and title 40, section 1508.27 of the Code of Federal Regulations.

*Ractopamine's Impact on Threatened or Endangered Species*

65. Elanco has acknowledged that ractopamine is moderately toxic to plants and slightly toxic to aquatic invertebrates.

66. When FDA adverse drugs reports for ractopamine are cross referenced with habitat data from the United States Fish and Wildlife Service, at least ninety-eight species of threatened and endangered aquatic invertebrates and plants have critical habit in areas where ractopamine is used.

67. Upon information and belief, FDA has never assessed the degree to which the approvals of ractopamine may adversely affect endangered and threatened species or their habitats in a publically available NEPA document as required under title 21, section 25.21(b), and title 40, section 1508.27(9) of the Code of Federal Regulations.

Combination Drugs

68. Ractopamine is often used in combination with other pharmaceuticals and usually administered through feed to all animals in a herd.

*Tylosin*

69. Tylosin is an antimicrobial first approved by FDA in 1961. *See* NADA 012-491, 26 Fed. Reg. 4369 (May 19, 1961). Tylosin is currently approved for growth promotion uses in poultry and pigs.

70. FDA considers tylosin "critically important" to human medicine.

71. Several studies have linked subtherapeutic use of tylosin at CAFOs to the development of tylosin-resistant bacteria.

72. The European Union has banned all growth promotion uses of tylosin because of its potential to render human antibiotics ineffective.

73. Tylosin was approved before Congress enacted NEPA. Upon information and belief, the only publically available NEPA document for tylosin analyzed a specific usage of tylosin—for the control of necrotic entiritis in broiler chickens over a five day period—and did not address the effects of tylosin when fed to cows, pigs, and turkeys, nor the effects associated with the challenged drugs at issue here.

74. A recent study calculated the total annual in-feed usage of tylosin in all phases of the U.S. pork industry as over 365,000 pounds, making the drug the second most-used in-feed antibiotic in the U.S. pork industry.

75. FDA records link tylosin to 32,738 reported adverse events in pigs, the second highest number of adverse events in pigs for any animal drug, after ractopamine. The combination of ractopamine with tylosin for use in pigs has also resulted in one of the highest number of adverse drug experiences, second only to un-mixed ractopamine.

76. Approximately 67% of tylosin fed to pigs is excreted through their manure. Tests have detected residual tylosin in manure slurries after eight months. A 2002 survey of surface waters in the United States found tylosin in 13.5% of streams sampled. Tylosin has a half-life of approximately 200 days in surface water.

77. A 2006 study published in Applied and Environmental Microbiology found "high levels of tylosin resistance persisted for years after usage" in soil.

78. A 2004 study in the Journal of Occupational and Environmental Hygiene found tylosin-resistant bacteria in the soil and air downwind of CAFOs, potentially exposing people in proximity to these facilities to large numbers of resistant forms of bacteria.

79. The approval of tylosin and ractopamine as a combination drug will result in increased usage of both drugs, and increase the total amount of those drugs in the food supply and the amounts of those drugs deposited in the environment.

80. Upon information and belief, FDA has never assessed the impact that widespread use of tylosin—especially in combination with other drugs, like ractopamine—may have on health, safety, or the environment, in a publically available NEPA document.

*Monensin*

81. Monensin is an antibiotic first approved in 1970. *See* NADA 38-878, 35 Fed. Reg. 7734 (May 20, 1970).

82. The European Union bans use of monensin for farm animal growth promotion.

83. Bovines fed monensin excrete 50% of the drug into the environment unchanged from its pre-feeding composition.

84. Studies have routinely detected monensin in CAFO wastewater and groundwater at cattle facilities.

85. A 2006 European Food Safety Authority report explained that available information suggests that the use of monensin in cattle for fattening at the maximum recommended dose, and under conditions typical for the use of a feed additive, will pose a risk for soil organisms.

86. A 2010 study concluded that even in low doses monensin has direct toxic effects on soil animals and presents a potential ecological risk.

87. Monensin affects different animal species differently. Exposure to even small amounts of it can kill non-target animals. Very small doses, less than 2 milligrams per kilogram

of body weight, can kill horses. Dogs, small ruminants, and ducks are also particularly sensitive to monensin.

88. The European Medicines Agency concluded that accidental ingestion of feed intended for turkeys or chickens containing monensin at the maximum authorized level present a health risk for several non-target animal species.

89. The approval of monensin and ractopamine as a combination drug will increase the use of both drugs, and increase the total amount of those drugs in the food supply and the amounts of those drugs deposited in the environment.

90. Upon information and belief, FDA has never assessed the impact that the use of monensin—especially in combination with other drugs, like ractopamine—may have on health, safety, or the environment, in a publically available NEPA document.

*Melengestrol*

91. Melengestrol is a steroidal female hormone first approved in 1968. 33 Fed. Reg. 2602 (Feb. 6, 1968).

92. A 2013 study found that melengestrol has "been detected in the environment near beef cattle feedlots," and may cause "alterations in growth and development" to exposed amphibians through endocrine-disrupting activity, although its "effects in aquatic organisms are virtually unknown."

93. Melengestrol can persist in soil fertilized with manure from cattle fed the drug for at least 195 days.

94. The European Union prohibits the use of melengestrol and other substances having a hormonal action for growth promotion because of the potential risks to human health from hormone residues in bovine meat.

95. The American Public Health Association and the Endocrine Society consider endocrine-disruptive compounds, including melengestrol, a significant threat to public health. Fetuses, infants, and children are thought to be more vulnerable to the hormone-disrupting effects of these hormone-like chemicals.

96. The approval of ractopamine and melengestrol as a new combination drug increases the total amount of those drugs in the food supply and the amounts of those drugs deposited in the environment.

97. Upon information and belief, FDA has never assessed the impact that widespread use of melengestrol—especially in combination with other drugs, like ractopamine—may have on health, safety, or the environment, in a publically available NEPA document.

98. The approval of ractopamine in various combinations with other drugs such as tylosin, monensin, and melengestrol increases the total amount of all of these drugs in the food supply and the environment.

99. Upon information and belief, FDA has never published a NEPA document that addresses the impacts of combining ractopamine with tylosin, monensin, or melengestrol on health, safety or the environment, as described above.

FDA's Initial Approvals of Ractopamine Based on Environmental Assessments

100. FDA has approved three animal drugs that are comprised entirely of ractopamine—Paylean (1999), Optaflexx (2003), and Topmax (2008)—based on cursory EAs and without preparing an EIS.

101. In 1999, FDA approved the use of ractopamine for pigs—under the trade name Paylean—based on an EA prepared by the applicant in 1995.

102. In 2003, FDA approved the use of ractopamine for cattle—under the trade name Optaflexx—based on an EA prepared by the applicant in 1998.

103. On December 1, 2008, FDA published in the Federal Register its approval of the use of ractopamine for turkeys as of November 12, 2008—under the trade name Topmax—based on an EA prepared by the applicant in 2001, and based on the Agency's finding that the action was not likely to have any significant environmental impacts.

104. Most of the analysis in those NEPA documents is now more than fifteen years old, and fails to account for significant new circumstances and information relevant to environmental concerns raised by the use of ractopamine, particularly the current widespread use of ractopamine and other feed additives.

105. In 1995, as part of the Paylean EA, Elanco estimated the concentration of ractopamine in soil based on pig producers' manure application rates at that time. Pig producers now apply two times more manure per acre than they did in 1998 because of lost cropland.

106. The 2001 FONSI for Optaflexx (ractopamine for cattle) noted "a possible chronic exposure risk from incremental increases in ractopamine hydrochloride from multiple site uses in cattle and swine feed" and "a high amount of uncertainty" about such chronic exposure risks. The 2001 FONSI provides no meaningful analysis of whether the use of ractopamine at cattle, pig, and turkey sites within the same watershed, and indeed throughout the United States, may create cumulatively significant impacts.

107. The NEPA documents accompanying the 2008 Topmax approval are similarly flawed. Although dated 2001, the Topmax EA relied upon nationwide turkey population data from 1998. This data was already five years out of date when FDA issued the FONSI in 2003, and ten years old when the Agency approved the drug in 2008.

108. Although the Topmax EA provides 1998 statistics for national turkey populations, the EA is never more granular than the state level. The data is now more than fifteen years out of date.

109. The Topmax EA fails to identify basic data to support an environmental analysis. It does not identify the leading turkey-producing state. Thus the EA provides no data that would allow FDA to identify any parklands, habitats, or imperiled species upon which the use of Topmax might have a significant impact as defined by the CEQ regulations.

110. The Topmax EA does not cite the CEQ regulations, much less examine the required intensity factors to determine whether the approval might have a significant environmental impact, and thus require an EIS.

111. The Topmax EA identifies potentially serious environmental impacts, but fails to analyze either their context or intensity, as required by NEPA and the CEQ regulations. For example, it notes without further analysis that ractopamine could enter the environment through turkey manure and runoff into aquatic systems. Within two days of eating Topmax, turkeys

excrete 95% of the administered ractopamine, but the EA provides no meaningful analysis of this data.

112. The Topmax EA calculates ractopamine soil concentration and potential runoff on the assumption that poultry litter is "mixed into the top 6 inches of soil homogenously" and only at levels optimized for phosphorus uptake. However, EPA states that "[p]oultry litter is normally surface applied" and only occasionally "incorporated into the soil" through tilling. If ractopamine-contaminated poultry litter is surface applied, the concentration of ractopamine in runoff would be much higher than the Topmax EA assumes. The EA makes no attempt to reconcile these issues, or inform the public of the actual environmental impact from surface application and runoff of ractopamine.

113. The Topmax EA also fails to address whether the use of ractopamine at cattle, pig, and turkey sites within the same watershed may create "cumulatively significant impacts" within the meaning of the CEQ regulations.

114. Contrary to the FONSI conclusion, the Topmax EA did not provide sufficient data to estimate impacts on any organisms "from the use of ractopamine in turkey alone or from concurrent use of approved products within a single watershed." Aside from a complete lack of state- or watershed-specific turkey population data, the Topmax EA provides zero baseline data regarding the population of pigs and cattle at the national, state, or watershed level. That missing baseline population data is essential to any estimate of potential environmental exposure from combined use at turkey, pig, and cattle facilities.

115. Although the U.S. turkey and cattle populations decreased some between 2001 and 2007, the U.S. pig population increased by nearly ten million animals during that time. In 2001 the total population of market-ready U.S. pigs was 51,292,000, by 2003 it was 52,231,000, and by 2008 it was 61,030,000.

116. The Topmax EA discusses a single "worst case scenario" for ractopamine environmental impacts to any given watershed, including potential concurrent use of the drug in turkeys, pigs, and cattle in a single watershed. The Topmax EA concludes "of all the uses or combinations of uses of ractopamine in a single watershed, the worst case scenario is one in

which runoff occurs from manure in a swine feedlot." The EA never explains how runoff from a single swine feedlot in a watershed could possibly be worse than concurrent manure mismanagement or spills from several swine feedlots and/or coincident watershed contamination from several swine facilities, several cattle facilities, and several turkey facilities.

117. The Topmax EA did not consider any alternatives to the proposed action, such as limiting the disposal of ractopamine-contaminated waste or restricting its use in areas that serve as habitat for threatened or endangered species. Instead, the EA states that "[t]he proposed action would not be expected to have any substantial adverse effect on human health or the environment. Therefore, alternatives to the proposed action do not need to be considered."

118. FDA failed to provide for any public or expert comment on its NEPA analysis for Topmax. FDA approved Topmax in September 2008. Coincident with its publication of the Topmax approval, FDA publicly released an EA prepared by Elanco seven years earlier in November 2001, which was never circulated for public or expert review of any kind. Likewise, FDA did not publically release the FONSI it signed in July 2003 until 2008.

FDA's Approval of New Ractopamine-Based Combination Drugs without NEPA Review

119. Since 2008, FDA has approved several new applications for ractopamine and ractopamine combination drugs such as melengestrol, monensin, and tylosin without any NEPA analysis whatsoever.

120. The FDA approvals challenged in this case include:

- 73 Fed. Reg. 72,714 (Dec. 1, 2008) (new application of ractopamine for turkeys).
- 73 Fed. Reg. 75,323 (Dec. 11, 2008) (new application of melengestrol, monensin, tylosin, and ractopamine for heifers fed in confinement for slaughter).
- 74 Fed. Reg. 66,914 (Dec. 17, 2009) (new application of tylosin and ractopamine for pigs).
- 75 Fed. Reg. 1275 (Jan. 11, 2010) (application of ractopamine for cattle).
- 75 Fed. Reg. 5887 (Feb. 5, 2010) (new application of monensin and ractopamine for turkeys).

- 75 Fed. Reg. 20,917 (Apr. 22, 2010) (new application of monensin, melengestrol, and ractopamine for heifers fed in confinement for slaughter).
- 75 Fed. Reg. 54,019 (Sept. 3, 2010) (new application of monensin, USP, tylosin, and ractopamine for cattle fed in confinement for slaughter).
- 78 Fed. Reg. 63,870 (Oct. 25, 2013) (generic versions of NADA 140–863 [ractopamine hydrochloride Type A medicated articles for pigs] and NADA 141–221, [ractopamine hydrochloride Type A medicated articles for cattle]).
- 79 Fed. Reg. 37,617 (Jul. 2, 2014) (generic versions of several previous name-brand ractopamine-based combination drugs).
- 79 Fed. Reg. 44,277 (Jul. 31, 2014) (generic versions of several previous name-brand ractopamine-based combination drugs).
- 79 Fed. Reg. 53,134 (Sept. 8, 2014) (generic versions of several previous name-brand ractopamine-based combination drugs).

121. For each approval, FDA relied on a "categorical exclusion" that consisted in its entirety of the following two sentences: "The agency has determined under 21 CFR 25.33 that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required." Among the approvals discussed herein, there are only minor, non-substantive changes to this wording.

122. FDA did not adequately explain how the approvals fit within the enumerated categorical exclusions of Section 25.33 of the Code of Federal Regulations. 21 C.F.R.

123. The approval of generic versions of ractopamine-based animal drugs—including combinations with drugs such as tylosin, monensin, or melengestrol—increases the total amount of all of these drugs deposited into the food supply and the environment.

124. A categorical exclusion of "[a] combination of previously approved animal drugs" is only appropriate "if the action does not increase the use of the drug." 21 C.F.R. § 25.33(a)(2).

125. Elanco originally represented to FDA in 1995 that ractopamine would be fed to at most 30% of 77 million American pigs (23,100,000 pigs per year). Today approximately 60% of 60.1 million American pigs are fed ractopamine (36,060,000 pigs per year).

126. For all of the approvals, FDA did not consider in the Federal Register notices whether the approvals would increase the use of ractopamine. Nor did the agency conclude that any of the approvals would "not increase the use of the drug."

127. Under CEQ regulations, categorical exclusions may only apply to actions "which do not individually or cumulatively have a significant effect on the human environment." 40 C.F.R. § 1508.4.

128. FDA never explained in the Federal Register notices for these approvals why they would not cumulatively effect the human environment.

129. None of the FDA's decisions explain whether there were "extraordinary circumstances" indicating that the approvals may significantly affect the quality of the human environment, and thus require "at least an EA." 21 C.F.R. § 25.21.

**FIRST CLAIM FOR RELIEF**

**FDA unlawfully approved Topmax in violation of NEPA and the APA.**

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

131. FDA's 2008 approval of Topmax is a major federal action that requires compliance with NEPA, and is subject to judicial review under the APA. 5 U.S.C. § 704.

132. NEPA requires agencies to consider both context and intensity to explain why a proposed action will not have a significant effect on the human environment. 40 C.F.R. § 1508.27.

133. FDA did not take the requisite "hard look" required by NEPA. FDA failed to consider the impacts of its approval in both context and intensity. The Topmax EA only considers Topmax's potential impacts at feedmills and Topmax use sites. It never considers the potential national human health and safety impacts, despite significant risk and concern of such impacts. Further, FDA never considered any of the factors required by agencies to determine the intensity of a proposed action's environmental impacts.

134. NEPA requires agencies to "rigorously explore and objectively evaluate" any reasonable alternatives to the proposed action. *Id.* § 1502.14(a); 42 U.S.C. § 4332(2)(E). The Topmax EA and 2003 FONSI failed entirely to consider alternatives to the proposed action.

135. NEPA requires public participation in all aspects of the NEPA process. 42 U.S.C. § 4332(2)(C); 40 C.F.R § 1500.1(b). FDA undertook the approval of Topmax, the Topmax EA, and FONSI without any public participation.

136. Alternatively, NEPA imposes a continuing duty on agencies to supplement previous environmental analysis and documentation. Agencies must prepare supplemental environmental analysis if "there are significant new circumstances and information relevant to environmental concerns and bearing on the proposed actions or its impacts." 40 C.F.R. § 1502.9(c)(1)(ii); 21 C.F.R. § 25.42(c).

137. FDA failed to at least prepare a supplemental EA in light of significant new circumstances that arose since Elanco first produced the Topmax EA in 2001. FDA failed to even evaluate whether significant new concerns existed that would require supplemental environmental analysis.

138. FDA's decision to approve Topmax was therefore arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with NEPA, 42 U.S.C. § 4332, and without observance of procedures required by law in violation of the APA, 5 U.S.C. §§ 701-706, and must be set aside.

## SECOND CLAIM FOR RELIEF

**FDA violated NEPA by approving applications for ractopamine-based combination drugs without any NEPA review.**

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

140. FDA's approvals of ractopamine-based combination animal drugs since December 11, 2008 are agency actions subject to judicial review under the APA. 5 U.S.C. § 704.

141. FDA approved ractopamine-based combination animal drugs since December 11, 2008 in violation of NEPA because the agency did not prepare an EIS or EA and FONSI for each

proposed action, and because the agency unlawfully relied upon categorical exclusions for those approvals.

142. A categorical exclusion from NEPA review is only appropriate "if the action does not increase the use of the drug." 21 C.F.R. § 25.33(a). FDA failed to adequately explain why the approvals would not increase the use of the drugs at issue. Because the drugs, by design, increase meat production, their approvals will necessarily result in increased use.

143. FDA regulations require at least an EA for any action that would normally be categorically excluded if that action potentially affects endangered or other protected species. 21 C.F.R. § 25.21. FDA never explained how it applied categorical exclusions to these combination drugs despite substantial evidence that ractopamine is moderately toxic to plants and slightly toxic to aquatic invertebrates. FDA never addressed the at least ninety-eight threatened and endangered species that have critical habitat in ractopamine use areas.

144. FDA may not rely on a categorical exclusion if extraordinary circumstances indicate that an action may significantly affect the quality of the human environment. *Id.* CEQ regulations require an agency to consider ten intensity factors to make this determination. 40 C.F.R. § 1508.27(b).

145. The facts outlined above indicate that FDA made these approvals despite evidence that the drugs at issue may significantly affect the quality of the human environment. Specifically, these facts indicate that these approvals may have adverse or beneficial impacts; public health or safety impacts; unique geographical impacts; highly controversial effects; highly uncertain risks; precedential effects; cumulatively significant impacts; adverse effects on threatened and endangered species or their habitat; and effects that threaten violations of environmental laws. *Id.*

146. FDA failed to consider the CEQ significance intensity factors and failed to explain why they did not apply. The Agency's decisions never even addressed whether these facts rendered the approvals ineligible for invocation of a categorical exclusion.

147. Alternatively, NEPA imposes a continuing duty on agencies to supplement previous environmental analysis and documentation. Agencies must prepare supplemental

environmental analysis if "there are significant new circumstances and information relevant to environmental concerns and bearing on the proposed actions or its impacts." 40 C.F.R. § 1502.9(c)(1)(ii); 21 C.F.R. § 25.42(c).

148. FDA failed to at least prepare supplemental EAs in light of significant new circumstances that arose since the original approvals and EAs and the time FDA issued FONSIs for these ractopamine-based combination drugs. FDA failed to even evaluate whether significant new concerns existed that would require supplemental environmental analysis.

149. FDA's approvals were therefore arbitrary and capricious, an abuse of discretion and not in accordance with NEPA, 42 U.S.C. § 4332, and without observance of procedures required by the APA, 5 U.S.C. §§ 701-706, and must be set aside.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request that the Court:

1. Declare that FDA's failure to comply with NEPA and the CEQ regulations before approving ractopamine-based animal drugs violates NEPA and the APA.
2. Vacate and remand FDA's decisions to approve ractopamine-based animal drugs without compliance with NEPA and the CEQ regulations.
3. Issue preliminary and permanent injunctive relief barring the use of ractopamine-based animal drugs until FDA complies with NEPA;
4. Award Plaintiffs fees, expenses, and costs pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412(d).
5. Grant Plaintiffs such further relief as is proper, just, and equitable.

DATED: November 6, 2014, in San Francisco, California.

/s/ Paige M. Tomaselli

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