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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE HUMANE SOCIETY OF THE UNITED STATES; UNITED FARM WORKERS OF AMERICA; ANIMAL LEGAL DEFENSE FUND, Plaintiffs, v. MARGARET A. HAMBURG, in her official capacity, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	Case No. _____

INTRODUCTION

1. This action challenges the Food and Drug Administration ("FDA")'s approval of several new animal drug applications containing ractopamine hydrochloride ("Ractopamine") – a controversial feed additive banned or restricted in dozens of nations, including China – without complying with the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4331, *et seq*.

2. Ractopamine is a nontherapeutic pharmaceutical fed to cattle, pigs, and turkeys to boost growth rates. While its manufacturer admits that Ractopamine is toxic to plants and aquatic invertebrates, the drug is used in at least 23 states that are known to provide habitat for threatened and endangered plants and aquatic invertebrates. Ractopamine exposure has also been linked to adverse health events in humans and animals, including abnormal heartbeat in humans and animals, and aggression, hyperactivity, broken limbs, collapse, and death in animals.

3. Between 2008 and 2014, FDA approved more than a dozen animal drugs that contain Ractopamine for use in hundreds of millions of pigs, turkeys, and cows. These approvals include new Ractopamine combination drugs that contain Tylosin, Monensin, and Melengestrol – controversial antibiotics and steroids.

4. Despite the far-reaching impacts of these decisions on millions of consumers, hundreds of millions of animals, millions of acres of habitat, and thousands of farm workers, FDA has never prepared an Environmental Impact Statement ("EIS") or even an Environmental Assessment ("EA") of the human

health, worker safety, and adverse environmental impacts of the widespread discharge of millions of pounds of Ractopamine and Ractopamine combination drugs into the environment each year.

5. For most of the Ractopamine combination drug applications at issue, the FDA conducted no NEPA analysis at all, but rather invoked a "categorical exclusion." For one application, a Ractopamine animal drug for turkeys, FDA reviewed a cursory EA prepared in 2001 by the drug company itself, which focused narrowly on the impacts of the limited use of Ractopamine alone on a small segment of the overall market, and made no attempt to address the cumulative impacts of the current use of Ractopamine in hundreds of millions of pigs, turkeys, and cattle slaughtered for food in the United States each year.

6. This suit seeks an order setting aside FDA's unlawful approvals of Ractopamine and Ractopamine combination animal drugs, and remanding this matter to FDA with instructions to carry out future approvals in accordance with the requirements of NEPA.

JURISDICTION AND VENUE

7. This Court has jurisdiction under 28 U.S.C. § 1331 and 5 U.S.C. § 701, *et seq*. Venue is proper under 28 U.S.C. § 1391(e) because Plaintiff Animal Legal Defense Fund resides in the Northern District of California.

PARTIES

8. Plaintiff The Humane Society of the United States ("HSUS") is a non-profit animal protection organization with millions of members and

constituents. HSUS advocates against unsustainable agricultural practices and the inhumane treatment of animals raised for food.

9. HSUS has a procedural interest in commenting on any Ractopamine-related NEPA documents, and an organizational interest in ensuring environmental, human health, and animal health risks of animal drugs are fully analyzed.

10. HSUS 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. HSUS members who eat meat also have a consumer interest in avoiding the health risks of drug-contaminated meat.

11. Plaintiff United Farm Workers of America ("UFW") is the nation's oldest and largest farmworker labor organization. UFW is headquartered in California and serves farmworkers throughout the country and maintains various offices in California, Oregon, and Washington.

12. UFW has represented farm workers for more than 50 years and currently has thousands of members, many of whom are migrant and seasonal farmworkers. UFW's mission is to protect and expand farmworkers' labor and employment rights, including rights pertaining to health and safety issues. UFW has represented, and continues to represent and/or assist, employees who are employed in the dairy, beef, and other livestock industries. UFW works to protect the health and safety of farmworkers from occupational injuries, including injuries caused by farm animals and exposure to pesticides and other dangerous compounds.

13. UFW has a procedural interest in commenting on any NEPA document concerning Ractopamine-based drugs, and an organizational interest in ensuring that the environmental and human health risks of animal drugs are fully analyzed.

14. UFW members and the workers it assists at livestock farms have a personal health and safety interest in protecting themselves from any adverse drug reactions from Ractopamine-based animal drugs while on the job, including increased animal aggression and exposure to dangerous pathogens that are resistant to critically important human antibiotics.

15. UFW members and workers that UFW assists at their workplaces also have a personal health and safety interest in protecting themselves and their families from the dangers the challenged livestock drugs pose to those who live near facilities where they are used. Antibiotic-resistant bacteria have been found in the soil and air downwind of facilities that use Tylosin, which means that UFW members and their families are at risk of increased exposure to dangerous pathogens that are resistant to even the most powerful antibiotics.

16. UFW members and farm worker communities have an aesthetic interest in keeping the areas where they live, work, hike, watch birds, swim, and live free of manure contaminated with Ractopamine, antibiotics, and steroids. UFW members who eat meat also have a consumer interest in avoiding any health risks of drug-contaminated meat.

17. Plaintiff Animal Legal Defense Fund ("ALDF") is a national non-profit organization headquartered in Cotati, California with more than 100,000

members and supporters. ALDF pursues its purpose of safeguarding animal welfare by persistently advocating for the protection of animals used and sold in commercial enterprises, including agriculture and agribusiness. ALDF frequently focuses on pollution to the environment caused by the inhumane confinement of farmed animals, and has expended significant organizational resources on advocacy and public education efforts to improve environmental and animal welfare conditions for animals.

18. ADLF has a procedural interest in commenting on any NEPA document concerning Ractopamine-based animal drugs, and an organizational interest in ensuring that the environmental and human health risks of animal drugs are fully analyzed.

19. ALDF 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. ALDF members who eat meat also have a consumer interest in avoiding any health risks of drug-contaminated meat.

20. Defendant Margaret A. Hamburg is the Commissioner of the FDA, an agency of the U.S. government responsible for approving animal drugs and for complying with NEPA.

STATUTORY AND REGULATORY FRAMEWORK

I. National Environmental Policy Act

21. NEPA is the "national charter for the protection of the environment." 42 U.S.C. § 4331 *et seq.;* 40 C.F.R. § 1500.1. "NEPA procedures must insure that environmental information is available to public officials and

citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b).

22. NEPA establishes three categories of agency action. First, agencies must prepare an EIS for "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C); 40 C.F.R. § 1501.4(a)(1). Second, agencies may "categorically exclude" from NEPA review classes of actions that "do not individually or cumulatively have a significant effect on the human environment." *Id.* §§ 1508.4, 1501.4(a)(2). But agencies must "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect." *Id.* § 1508.4. Third, agencies must prepare an EA for proposed actions that do not fit into either of the first two categories. *Id.* §§ 1501.4(b), 1508.9.

23. If the EA indicates that the proposed action "will not have a significant effect on the human environment," the agency can issue a Finding of No Significant Impact ("FONSI"). *Id.* § 1508.13. If, however, the EA indicates that the proposed action may significantly affect the quality of the human environment, the agency must then prepare an EIS.

24. NEPA and its implementing regulations further require that agencies must "[r]igorously explore and objectively evaluate all reasonable alternatives." 40 C.F.R. § 1502.14(a); 42 U.S.C. § 4332(2)(E).

25. NEPA and its implementing regulations also require public participation. *See* 42 U.S.C. § 4332(C); 40 C.F.R. § 1500.1(b) ("NEPA procedures

must insure that environmental information is available to the public officials and citizens before decisions are made and before actions are taken.").

II. The Administrative Procedure Act

26. The Administrative Procedure Act ("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

I. Impacts of Ractopamine on Health, Safety, and the Environment

A. Background on Ractopamine

27. Elanco (a division of Eli & Lilly) markets Ractopamine as a feed additive to induce faster growth and leaner meat in pigs, cattle, and turkeys. It is a phenethanolamine beta-adrenoceptor agonist ("beta agonist"), a pharmacological agent that shifts dietary energy toward muscle growth as opposed to fat deposition. Because the drug causes more muscle mass accumulation than would otherwise occur, it allows the pork, beef, and turkey industries to generate a greater profit and decrease feed costs.

28. Beta-agonists cause a number of side effects in farm animals. For example, Ractopamine has been shown to speed up an animal's heart rate as a consequence of elevated catecholamine stress hormones. Ractopamine can also cause a number of behavioral changes in animals, including an increase in activity and aggressiveness.

29. Ractopamine is linked to a variety of adverse drug effects, including hyperactivity, trembling, broken limbs, inability to walk, dyspnea (difficulty in breathing), and even death.

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

31. Ractopamine is controversial because of the potential human health risks associated with its use in food animals. FDA based its original safety approval 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. In 2002, three years after FDA first approved Ractopamine, the FDA Center for Veterinary Medicine Office of Surveillance and Compliance sent Elanco a letter accusing the company of withholding information about the drug's "adverse animal drug experiences" and "safety and effectiveness."

32. The FDA letter noted the "unusual failure" of the drug "to exhibit its expected pharmacological activities." FDA Warning Letter to Elanco Animal Health (Sept. 12, 2002). FDA also required Elanco to add warning labels that state "CAUTION: Ractopamine may increase the number of injured and/or fatigued pigs during marketing." 21 C.F.R. § 558.500(d)(ii).

33. Because of human safety concerns, dozens of nations, including all European Union members, China, and Russia, prohibit or restrict Ractopamine use in food animals.

34. FDA approved Ractopamine for use in pigs in 1999 under the brand name Paylean, and subsequently approved Ractopamine for cattle and turkeys under the brand names Optaflexx and Topmax, respectively. Since its initial approval as Paylean, Ractopamine use has increased significantly in the pork, beef, and turkey industries.

35. Elanco originally predicted Ractopamine would achieve "[a]n optimistic market penetration of 30%" of American pigs. Today, Ractopamine is fed to approximately 60% to 80% of pigs, cattle, and turkeys raised in the United States.

36. Zilmax, the primary cattle feed drug in competition with Ractopamine, was voluntarily withdrawn from the market in August 2013 after major beef packers indicated they would no longer process Zilmax-drugged cattle. Because 60% to 80% of cattle are fed beta agonists such as Zilmax and Ractopamine, and because Zilmax is no longer on the market, industry experts reasonably expect use of Ractopamine in cattle to have increased significantly since August 2013.

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

B. Food Safety Risks Associated with Ractopamine

38. The connection between foodborne illness and the conditions in animal factories is well-documented. Virtually all pork and over 75% of beef consumed in the U.S. comes from large-scale confined animal feeding operations, or CAFOs.

39. Each year, 128,000 Americans are hospitalized and 3,000 are killed by foodborne illness. Foodborne *Salmonella* hospitalizes nearly 20,000 Americans each year.

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

41. Ractopamine has been associated with more adverse events in pigs than any other animal drug on the market between 1987 and 2011, with 218,116 reported adverse events in pigs (160,917 of these pigs were sickened or killed).

42. Common adverse events reported were trembling, lameness, recumbency, reluctance to move, stiffness, hyperactivity, hoof disorder, dyspnea, collapse, and death. Examples of these adverse events include:

- "Producer reported that he plans to stop using ractopamine because he has had 10 to 12 deads on trucks. Previously had 1-2 deads 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 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, weak and slow to move. 1 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."

43. Pigs fed Ractopamine are also more susceptible to stress. Research shows that pigs fed Ractopamine had increased concentrations of stress hormones, which can significantly increase the presence of *E. coli* and *Salmonella*.

44. In one study, researchers applied a typical dose of Ractopamine given to feedlot steers and finishing pigs to bacteria in vitro. The researchers found that the addition of Ractopamine significantly increased the growth rate for *Salmonella*.

45. 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 in transit to and at slaughter facilities — exposing workers to safety risks. Such collapsed pigs are also significantly more likely to contract *E. coli*, *Salmonella*, and *Campylobacter* in transport and at slaughter, which in turn increases food safety risks.

46. Virtually all Ractopamine-treated pigs that collapse at slaughterhouses will be moved to "suspect pens" and may be held indefinitely before being slaughtered. Several studies establish that moving these pigs into suspect pens increases the risk of *Salmonella* and other infections.

47. 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. This infection risk correlates to increased risk of dangerously adulterated meat making its way to consumers.

48. A recent Consumer Reports test of 240 U.S. pork products found that about one in five tested positive for Ractopamine residues.

49. FDA has never adequately assessed the impacts of Ractopamine on food safety described above in a publicly available NEPA document.

C. Worker Safety Risks Associated with Ractopamine

50. Several studies have found that Ractopamine makes pigs more aggressive. A 2010 study published in the *Journal of Animal Science* found that pigs fed Ractopamine are more likely to attack, bite, and injure other pigs. Pig aggression is a leading cause of injury for workers in the pork industry.

51. Because pigs fed Ractopamine can be difficult to move, they are more likely to induce human handlers to use more harsh handling methods for routine procedures. A 2003 study published in the *Journal of Animal Science* 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, such as when they do not exit their pens voluntarily.

52. Plaintiff UFW's members handle Ractopamine and Ractopamine-treated feed for agricultural purposes. Every year, UFW members and workers that are employed in the livestock industry are exposed to Ractopamine in ways that can cause severe poisoning and necessitate emergency medical attention. FDA records of adverse events reveal that even minor physical contact with this over-the-counter drug—such as touching it—can require emergency medical attention.

53. For example, below are a few of the adverse events FDA has recorded regarding handling Ractopamine:

- Ractopamine "end user contacted [Rocky Mountain Poison and Drug Center]…Reported having respiratory problems since exposure. Was referred to MD. Protective gear recommended when using product…User again contacted RMPDC, reported that 20 min. after exposure he experienced 'heart flutters' but thought they might have been back spasms. Also had intermittent dizziness x 3 weeks."

- A man "fed Ractopamine for the first time…between 7 to 11am. Shortly after, he was admitted to the ER with a high heart rate. Spent the whole day on a cardiac monitor. At time of the call to [Rocky Mountain Poison and Drug Center] the man was home with a slightly elevated HR. Mixing the Ractopamine was the only thing different he had done that day. He had used protective gear but unsure if he showered after exposure."

The continued exposure of UFW's members and other farm workers to the harmful effects of Ractopamine are a direct result of FDA's drug approvals.

54. FDA has never adequately assessed the impacts of Ractopamine on worker safety described above in a publicly available NEPA document.

D. The Environmental Impacts of Ractopamine

55. Ractopamine enters the environment mainly through livestock manure. "According to the U.S. Department of Agriculture, confined food animals produce roughly 500 million tons (dry weight) of waste per year, which is more than 65 times the mass of human biosolids generated by publicly owned treatment works (7.6 million tons in 2005)." E. Silbergeld, et al., "Industrial Food Animal Production, Antimicrobial Resistance, and Human Health," 29 Annu. Rev. Public Health 151, 159-160 (2008) (internal citations omitted).

56. Essentially all Ractopamine fed to cattle, pigs, and turkey is excreted into their manure. Thus, by multiplying the respective dosage amounts for pigs, cattle, and turkeys by the percentage of each species given the drug, and using the total number of each species slaughtered each year, it is possible to estimate approximately how much Ractopamine is introduced into the environment each year.

57. For example, 112,126,000 pigs were slaughtered in the U.S. in 2013, and the Ractopamine dosage for these pigs is 3.0 g/animal. If 60% of those pigs were fed Ractopamine, then approximately 201,826.8 kg (222.476 tons) of active Ractopamine was likely excreted. If 70% of those pigs were fed Ractopamine, the amount excreted would be 235,464.6 kg (259.555 tons).

58. For turkeys, 239,385,000 were slaughtered in the U.S. in 2013, and they may be dosed at 0.202 g/hen or 0.349 g/tom. Assuming 55% of the population are toms, 45% are hens, and assuming 60% of the total population are fed Ractopamine, that results in approximately 40,626 kg (44.7826 tons) of Ractopamine excreted in 2013, or 47,397 kg (52.2464 tons) if 70% of the turkeys were administered the drug.

59. For cattle, 32,459,000 were slaughtered in the U.S. in 2013, and the dosage of Ractopamine for cattle is 13.7 g/animal. If 60% of that population were fed Ractopamine, then approximately 266,813 kg (294.111 tons) should have been excreted, and if 70% were fed Ractopamine, the total jumps to 311,281.8 kg (343.129 tons) in a single year.

60. Accordingly, for just one year, the combined population of Ractopamine-drugged pigs, cattle, and turkeys may excrete over a million pounds of the drug, the vast majority of which was released directly into the environment.

61. Most Ractopamine-laced pig, turkey, and cattle manure is generated at CAFOs, which lack sufficient land to absorb the manure. Livestock producers often store this manure in massive open-air lagoons, and they attempt to dispose of it—without treatment to remove Ractopamine—through application to nearby fields ("application") or through a process of in-ground injection ("injection").

62. These methods can and often do contaminate groundwater, streams, rivers, and other surface waters. "Emerging scientific data . . . suggests that pollution of rivers, lakes, and streams by active drug residues presents a significant, adverse impact on the aquatic environment." Shawna Bligh, *Pharmaceuticals in Surface Waters: Use of NEPA*, American Bar Association: Natural Resources & Environment Publication (2009).

63. Elanco acknowledges the risk of Ractopamine-laced waste "leaching into the soil and groundwater from confinement areas … and runoff from land fertilized with manure from treated animals." Topmax EA, 14. Elanco also acknowledges that 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 publicly released field study of Ractopamine's impact on the chemical composition of waterways.

64. Nationally, CAFOs confine millions of animals and their waste products, yet not all of those facilities maintain environmental permits. As of 2012, for example, the Environmental Protection Agency ("EPA") has estimated that there may be over 20,000 animal confinement facilities that meet the Clean Water Act's CAFO definition, 40 C.F.R. § 122.23(b). However, just over 7,000 of those facilities maintain Clean Water Act permits. Accordingly, the majority of CAFOs may be discharging manure in potential violation of state and federal law.

65. The EPA has found 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."

66. FDA has never adequately assessed the impacts of Ractopamine on health and safety described above in a publicly available NEPA document.

E. Ractopamine's Impact on Threatened or Endangered Species

67. By cross-referencing FDA's adverse drugs reports for Ractopamine with U.S. Fish and Wildlife Service ("FWS") habitat data, Plaintiffs have identified at least 98 species of threatened and endangered aquatic invertebrates and plants that have critical habit in areas in 23 states where Ractopamine is used.

68. Elanco has acknowledged that Ractopamine is moderately toxic to plants and slightly toxic to aquatic invertebrates.

69. For example, adverse drug reports show that Ractopamine is used in Clayton County, Iowa. Clayton County has more than an estimated 260,000 pigs and 69,000 cattle. Clayton County is also listed as habitat for several species of threatened and endangered aquatic invertebrates and plants, including the Sheepnose Mussel and the Western prairie fringed Orchid.

70. Aquatic invertebrates such as freshwater mussels are important food sources for wildlife, including otters, raccoons, ducks, wading birds, and fish. Animals that depend on aquatic invertebrates for food, such as the Yuma Clapper Rail, a wading bird found in California, Arizona, and Nevada are also federally listed endangered species.

71. FWS identifies the monarch butterfly as an important pollinator that is threatened by the loss of milkweed in its breeding habitat, largely located in the Midwestern Corn Belt. Ractopamine is extensively used in agricultural operations across the Corn Belt, and is moderately toxic to plants like milkweed. There has been a conspicuous decline in monarch butterfly populations since Ractopamine's original approval in 1999.

72. FDA has never assessed the impacts of Ractopamine on endangered species or their habitats described above in a publicly available NEPA document.

II. Impacts of Combining Ractopamine With Other Animal Drugs

A. Tylosin

73. Tylosin is an antimicrobial first approved in 1961. 26 F.R. 4359 (May 19, 1961). Tylosin is administered to approximately 71% of cattle in feedlots, and is additionally approved for growth promotion uses in poultry and

pigs. The European Union has banned all growth promotion uses of Tylosin because of its potential to render critical human antibiotics ineffective.

74. FDA considers macrolides, which include Tylosin, "critically important" to human medicine. In 1969, a Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine chartered by the U.K. Parliament recommended that Tylosin should not be available as a growth promoter.

75. Tylosin was approved before NEPA was enacted. Upon information and belief, the only publicly available NEPA document for Tylosin analyzed a specific usage of Tylosin—for the control of necrotic enteritis 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.

76. A recent study calculated the total annual usage of Tylosin by the U.S. pork industry to be 365,533 pounds, 158,995 pounds of which are used in the growing/finishing phase alone – making the drug the second most-used antibiotic in the industry.

77. Approximately 67% of Tylosin administered to pigs is excreted. Residual Tylosin has been detected in manure slurries after eight months. In a 2002 survey of surface waters in the United States, Tylosin was found in 13.5% of streams sampled. In surface water Tylosin has a half-life of approximately 200 days. Tylosin has been identified as having a high potential to be released into the environment.

78. Between 1987 and 2011, Tylosin was involved in 32,738 reported adverse events in pigs — one of the highest number of adverse events in pigs for any animal drug during that timeframe.

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

80. Tylosin-resistant bacteria have been found in the soil and air downwind of CAFOs, and "[p]eople in proximity to these facilities could potentially be exposed to large numbers of resistant forms of bacteria," according to a 2004 study published in the *Journal of Occupational and Environmental Hygiene*.

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

82. The antibiotic resistance-related harms Tylosin poses are a grave concern to farm workers, including UFW members, because they are exposed to Tylosin not only at work but also in their homes, as they typically live near the facilities in which they work.

83. The approval of Ractopamine and Tylosin as a new combination drug increases the total amount of both drugs deposited into the food supply and the environment.

84. FDA has never assessed the impact that widespread use of Tylosin — especially in combination with other drugs — may have on health, safety, or the environment, in a publicly available NEPA document.

B. Monensin

85. Monensin is an antibiotic first approved in 1970. 35 Fed. Reg. 7734 (May 20, 1970). The European Union bans use of Monensin for cattle growth promotion.

86. Ionophore antibiotics, which include Monensin, are administered to approximately 90% of cattle in large feedlots. Where Monensin is used as a feed additive for lactating dairy cows, it is typically the most relied upon antibiotic. Approximately half of all dairy farms in California use Monensin.

87. Approximately 40 to 50% of Monensin fed to bovines is excreted into the environment unchanged from its pre-feeding composition. A 2006 European Food Safety Authority report explained 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 (continuous use) will pose a risk for soil organisms.

88. A 2010 study concluded that, even in low doses, Monensin had direct toxic effects on soil animals and presents a potential ecological risk.

89. Monensin has been detected in CAFO wastewater and groundwater at cattle facilities.

90. Coincident with FDA's repeated approvals of drugs containing Monensin, freshwater mussels throughout the Midwest have been approaching extinction at an unparalleled rate. The zooplankton that these mussels depend on can be severely impacted by Monensin use. The U.S. Fish and Wildlife Service has said of fresh water mussels "[n]o other group of animals in North

America is in such grave danger of extinction!" More than 40% of the 300 North American species of freshwater mussels are in danger of extinction. Minnesota, Wisconsin, Iowa, Missouri, Illinois, Indiana, and Ohio list more than half of their 78 known mussel species as endangered, threatened, or requiring special concern. Mussels are eaten by ducks, wading birds, and fish — some of which are federally listed endangered species.

91. Studies establish that Monensin concentrations in water above .05 ppm can negatively impact zooplankton, which are vital to the health of ecosystems. The concentration of Monensin typically excreted in cattle manure is many times higher than this. Monensin has been detected at dangerously high levels in surface waters near dairy and feedlot operations.

92. In looking at the risks and impacts of accidental Monensin exposures, the European Food Safety Authority concluded "accidental ingestion of feed intended for turkeys or chickens containing Monensin at the maximum authorised level of 120 and 125 mg/kg feed, respectively, presents a health risk for several non-target animal species." Cross-contamination of non-target feedingstuffs by monensin authorised for use as a feed additive Scientific Opinion of the Panel on Contaminants in the Food Chain, 2 (2007).

93. The approval of Ractopamine and Monensin as a new combination drug increases the total amount of both drugs deposited into the food supply and the environment.

94. FDA has never assessed the impact that widespread use of Monensin — especially in combination with other drugs — may have on health, safety, or the environment, in a publicly available NEPA document.

C. Melengestrol

95. Melengestrol is a synthetic steroid hormone first approved in 1968. 33 Fed. Reg. 2602 1968.

96. More than half of U.S. feedlots that place heifers on feed use Melengestrol as a supplement.

97. A recent 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."

98. 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.

99. 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 hormone-like chemicals.

100. The approval of Ractopamine and Melengstrol as a new combination drug increases the total amount of both drugs deposited into the food supply and the environment.

101. FDA has never assessed the impact that widespread use of Melengstrol — especially in combination with other drugs — may have on health, safety, or the environment, in a publicly available NEPA document.

102. The approval of Ractopamine in various combination drugs such as Tylosin, Monensin, or Melengestrol increases the total amount of all of these drugs deposited into the food supply and the environment.

103. FDA has never published a NEPA document that addresses the impacts of combining Ractopamine with Tylosin, Monensin, or Melengestrol on health, safety, and the environment, as described above.

III. FDA's Initial Approvals of Ractopamine Based on Environmental Assessments

104. Between 1999 and 2003, FDA approved three animal drugs that are comprised entirely of Ractopamine — Paylean (1999), Optaflexx (2003), and Topmax (2008) — based on cursory environmental assessments, and without preparing an EIS.

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

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

107. In 2008, the FDA approved the use of Ractopamine for turkeys – under the trade name Topmax – based on an EA prepared by the applicant in

2001, and based on the agency's 2003 finding that the action was not likely to have any significant environmental impacts.

108. Most of the analysis in those NEPA documents is more than 15 years old, and fails to even account for the current widespread use of Ractopamine and the other feed additives at issue.

109. For example, 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 significantly more manure per acre than they did in 1998.

110. Likewise, 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, but made no attempt to provide a meaningful analysis of whether the use of Ractopamine at multiple cattle, pig, and turkey sites within the same watershed, and indeed throughout the United States, may create cumulatively significant impacts.

111. The NEPA documents accompanying the 2008 Topmax approval are similarly flawed. For example, although dated 2001 the Topmax EA relied upon nationwide turkey population data from 1998, which was 5 years out of date when FDA issued the FONSI in 2003, 10 years old when the agency approved the drug in 2008, and now more than 15 years out of date. Topmax EA, 10.

112. The Topmax EA also fails to even identify basic, baseline data to support an environmental analysis. It does not identify the leading turkey

producing states, and provides no data that would allow FDA to identify any parklands, habitats, or imperiled species that the use of Topmax might have a significant impact upon within the meaning of the CEQ regulations.

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

114. 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.

115. In addition to 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.

116. The Topmax EA also did not consider any alternatives to the proposed action—including 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." Topmax EA at 41.

117. The FDA also apparently 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 apparently never circulated for public or expert review of any kind. Likewise, the FONSI signed by FDA in July 2003 was also not publicly released until 2008.

IV. FDA's Approval of New Ractopamine and Ractopamine Combination Drugs Without Any NEPA Review

118. Since 2008, FDA has approved several new applications for Ractopamine in combination with other drugs such as Melengestrol, Monensin, and Tylosin without any NEPA analysis.

119. The FDA approvals lacking any NEPA review that are challenged in this case include:

- 73 F.R. 75323 (Dec. 11, 2008) (supplement to generic copy of Ractopamine, Monensin, generic Melengestrol, and Tylosin combination for use in heifers).
- 74 F.R. 66914 (Dec. 17, 2009) (supplement to Ractopamine and Tylosin combination for use in pigs).
- 75 F.R. 1275 (Jan. 11, 2010) (supplement to Ractopamine for use in cattle).
- 75 F.R. 5887 (Feb. 5, 2010) (Ractopamine and Monensin combination for use in turkeys).
- 75 F.R. 20917 (Apr. 22, 2010) (supplement to generic copy of Ractopamine, Monensin, and generic Melengestrol combination for use in heifers).

- 75 F.R. 54019 (Sept. 3, 2010) (supplement to Ractopamine and Monensin combination for use in cattle; supplement to Ractopamine, Monensin, and Tylosin for use in cattle).

- 78 F.R. 63870 (Oct. 25, 2013) (generic copy of Ractopamine for use in pigs; generic copy of Ractopamine for use in cattle).

- 79 F.R. 37617 (Jul. 2, 2014) (generic copy of Ractopamine and generic Tylosin combination for use in pigs; generic copy of generic Ractopamine and Tylosin combination for use in pigs; generic copy of generic Ractopamine, Monensin, and Tylosin combination for use in cattle).

- 79 F.R. 44277 (Jul. 31, 2014) (generic copy of generic Ractopamine, Monensin, Tylosin, and Melengestrol combination for use in cattle; generic copy of generic Ractopamine, Monensin, and Melengestrol combination for use in cattle).

- 79 F.R. 53134 (Sept. 8, 2014) (generic copy of Ractopamine, Monensin, generic Tylosin, and Melengestrol combination for use in cattle; generic copy of Ractopamine, Monensin, and generic Tylosin combination for use in cattle; generic copy of generic Ractopamine and Monensin combination for use in cattle).

120. For each approval, FDA invoked a "categorical exclusion" that relied on a cursory, two sentence statement such as, "[t]he agency has determined under 21 C.F.R 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 CE approvals described herein, there are only minor, mostly non-substantive changes to this wording.

121. For the 2009-2013 approvals listed above, FDA did not explain which of the enumerated categorical exclusions listed in 21 C.F.R. § 25.33 it relied on, or how the approvals fit within any of these exceptions.

122. For the remaining approvals listed above, FDA invoked either 21 C.F.R. § 25.33(a)(1)(providing for the categorical exclusion of "[a]n animal drug to be marketed under the same conditions of approval as a previously approved animal drug.") or 21 C.F.R. § 25.33(a)(2)(providing for the categorical exclusion of "[a] combination of previously approved animal drugs"). A categorical exclusion is only appropriate under these provisions of 21 C.F.R. § 25.33(a) "if the action does not increase the use of the drug."

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. Although Elanco originally represented to FDA in 1995 that Ractopamine would be fed to, at most, 30% of American pigs, approximately 60%-80% of American pigs are now fed Ractopamine, and there are millions more pigs now than there were twenty years ago when this assessment was made.

125. For all of the categorical exclusion 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."

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

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

128. 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.

CLAIMS FOR RELIEF

Claim One: FDA Acted Unlawfully in Approving Topmax Without Adequate Compliance with NEPA

129. The allegations of all prior paragraphs are incorporated by reference.

130. The 2008 approval of Topmax violates NEPA and the CEQ implementing regulations because the FDA did not prepare an EIS for the proposed action, and because the Topmax EA and 2003 FONSI (1) failed to explain why the proposed action will not have a significant effect on the human environment; (2) failed to consider cumulative impacts; (3) refused to consider alternatives to the proposed action; and (4) were undertaken without any public participation, as mandated by NEPA and the CEQ regulations.

131. The decision to approve Topmax was therefore arbitrary and capricious, an abuse of discretion, and not in accordance with NEPA, 42 U.S.C. § 4332; 40 C.F.R. 1502.9(c), and must be set aside. 5 U.S.C. §§ 701-706.

Claim Two: FDA Violated NEPA By Approving Applications For Ractopamine Combination Animal Drugs Without Any NEPA Review

132. The allegations of all prior paragraphs are incorporated by reference.

133. The FDA's approvals of Ractopamine and Ractopamine combination animal drugs since December 11, 2008 were issued in violation of NEPA because the agency did not prepare an EIS or EA and FONSI for each proposed action, and because the Categorical Exclusions relied upon by the agency were unlawful.

134. The relied-upon Categorical Exclusions were unlawful because the actions increase the use of the drug at issue, 21 C.F.R. § 25.33(a), and because the decisions (1) affect endangered or other protected species, 21 C.F.R. § 25.21; (2) affect other "significance factors" requiring the preparation of at least an EA under the CEQ regulations, 40 C.F.R. § 1508.27(b); and (3) never even addressed whether these facts render the approval decisions ineligible for invocation of a Categorical Exclusion.

135. The decisions were therefore arbitrary and capricious, an abuse of discretion, and not in accordance with NEPA, 42 U.S.C. § 4332; 40 C.F.R. 1502.9(c), and must be set aside. 5 U.S.C. §§ 701-706.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

A. Declare that FDA's failure to comply with NEPA and the CEQ regulations before approving Ractopamine and Ractopamine combination animal drugs violates NEPA and the APA;

B. Vacate and remand FDA's decisions to approve Ractopamine and Ractopamine combination animal drugs without compliance with NEPA;

C. Award Plaintiffs' fees, expenses, and costs;

D. Grant Plaintiffs such further relief as is proper, just, and equitable.

November 6, 2014

Respectfully submitted,

___/s/_____

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Counsel for The Humane Society of the United States, United Farm Workers of America, and the Animal Legal Defense Fund

JS 44 (Rev. 12/12) cand rev (1/15/13)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
The Humane Society of the U.S., United Farm Workers of America, Animal Legal Defense Fund

(b) County of Residence of First Listed Plaintiff Washington, D.C.
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jonathan R. Lovvorn, Humane Society of the U.S., 2100 L St., NW Washington DC, 20037 202-955-3669

DEFENDANTS
Margaret A. Hamburg, in her official capacity, Commissioner, U.S. Food & Drug Agency

County of Residence of First Listed Defendant Washington, D.C.
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
5 U.S.C. 701; 42 U.S.C. 4331
Brief description of cause:
Action for review of final agency actions of the U.S. Food & Drug Agency.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE 11/06/2014 SIGNATURE OF ATTORNEY OF RECORD

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) ☑ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA