

**CITIZEN PETITION TO THE FOOD AND DRUG ADMINISTRATION**

Food and Drug Administration  
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Petitioners, )  
)  
v. ) Docket Number \_\_\_\_\_  
)  
**Filed With:** )  
)  
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December 20, 2012

**CITIZEN PETITION  
SEEKING AGENCY REVIEW OF CODEX STANDARDS ON RACTOPAMINE**

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## ACTIONS REQUESTED

Pursuant to the Petition Clause in the First Amendment of the United States Constitution;<sup>1</sup> the Administrative Procedure Act (“APA”);<sup>2</sup> the Food and Drug Administration (“FDA”)’s implementing regulations;<sup>3</sup> FDA regulations pertaining to the standards (“Codex Standards”) of the Codex Alimentarius Commission (“Codex”);<sup>4</sup> the Federal Food, Drug, and Cosmetic Act (“FFDCA”);<sup>5</sup> and the new animal drug provisions of the FFDCA,<sup>6</sup> Petitioners submit this citizen petition (the “Petition”) for rulemaking and collateral relief under the authority of 21 U.S.C. § 360b, 21 C.F.R. § 130.6, and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to undertake the following actions:

- (1) Immediately review the Codex Standards standards for ractopamine as established in July 2012;
- (2) Publish this Petition in the Federal Register as a proposal;
- (3) Provide opportunity for public comment on the Petition;
- (4) Perform comprehensive scientific studies needed to characterize the health, welfare, and behavioral risks posed by the use of ractopamine in food-producing animals, including studies of animal toxicity of the drug with its metabolites (including, but not limited to, their genotoxicity, carcinogenicity, and any cardiovascular, reproductive,

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<sup>1</sup> “Congress shall make no law . . . abridging . . . the right of the people . . . to petition the Government for a redress of grievances.” U.S. Const. amend. I. The right to “petition for a redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights.” *United Mine Workers of Am. Dist. 12 v. Ill. State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and “has a sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). “[A]ny attempt to restrict those liberties must be justified by the clear public interest, threatened not doubtful or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in and fundamental to the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1875).

<sup>2</sup> 5 U.S.C. § 553(e).

<sup>3</sup> 21 C.F.R. §§ 10.20, 10.30.

<sup>4</sup> 21 C.F.R. § 130.6.

<sup>5</sup> 21 U.S.C. §§ 301-399f.

<sup>6</sup> 21 U.S.C. § 360b (new animal drug provisions).

endocrine, musculoskeletal, or behavioral effects they may elicit); animal behavioral effects of the drug (including but not limited to social behaviors); and animal exposure to residues of the drug and its metabolites in edible tissues;

- (5) Perform comprehensive scientific studies needed to characterize human food safety risks posed by the use of ractopamine in food-producing animals, including studies of human toxicity of the drug with its metabolites (including, but not limited to, their genotoxicity, carcinogenicity, and any cardiovascular, reproductive, endocrine, musculoskeletal, or behavioral effects they may elicit); and human exposure to residues of the drug and its metabolites in the edible tissues of food-producing animals;
- (6) Perform comprehensive scientific studies to characterize the environmental risks posed by the use of ractopamine in food-producing animals; and
- (7) Pending Codex review and comprehensive scientific study, significantly strengthen U.S. standards by:
  - a. Deviating from Codex standards for ractopamine and setting more health- and welfare-based standards;  
  
or, in the alternative if FDA determines it will not or cannot perform this act:
  - b. Meeting Codex standards for ractopamine.

## **INTRODUCTION**

Ractopamine, or ractopamine hydrochloride, is an off-white to-cream colored solid drug in the beta-agonist pharmacological class<sup>7</sup> that induces increased heartbeat, relaxing of blood vessels, smooth muscle relaxation, and contraction of cardiac tissue in animals. The drug is widely used in U.S. food production systems. Ractopamine enhances animal growth by inhibiting fat growth, stimulating lipolysis,

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<sup>7</sup> The beta-agonist class also includes clenbuterol. Food Safety & Inspection Serv., U.S. Dep't of Agric., *Clenbuterol* (July 1995), <http://www.fsis.usda.gov/oa/background/clenbute.htm>. Many nations, including the U.S., have prohibited the use of clenbuterol, which is reported to induce negative effects in humans including increased heart rate, muscle tremors, headache, nausea, fever, and chills. *Id.*

increasing protein synthesis, and reducing protein breakdown in muscle.<sup>8</sup>

Ractopamine is linked to significant health problems and behavioral changes in animals, such as cardiovascular stress, muscular skeletal tremors, “downer” animals, increased aggression, and hyperactivity.<sup>9</sup> Most beta-agonist drugs are already prohibited for use in animal feed.<sup>10</sup> Furthermore, studies suggest that ractopamine may also be detrimental to human health and possibly to the environment.

In response to new animal drug applications, FDA first approved the use of ractopamine as a new animal drug in 2000 for use in pigs.<sup>11</sup> In the initial approval, FDA concluded that an environmental impact statement was not required. At the same time, FDA inconsistently concluded that there was a “high amount of uncertainty” associated with its observations of the risks of chronic exposure to ractopamine.<sup>12</sup>

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<sup>8</sup> J.P. Wang, S.X. Zhang & J.Z. Shen, *Technical Note: A Monoclonal Antibody-Based Immunoassay for Determination of Ractopamine in Swine Feeds*, 84 J. of Animal Sci. 1248, 1248 (2006).

<sup>9</sup> R. Poletto et al., *Aggressiveness and Brain Amine Concentration in Dominant and Subordinate Finishing Pigs Fed the  $\beta$ -Adrenoreceptor Agonist Ractopamine*, 88 J. of Animal Sci. 3107, 3118 (2010), available at <http://www.animal-science.org/content/88/9/3107.full.pdf>; R. Poletto et al., *Behavior and Peripheral Amine Concentrations in Relation to Ractopamine Feeding, Sex, and Social Rank of Finishing Pigs*, 88 J. of Animal Sci. 1184, 1184 (2009), available at <http://www.animal-science.org/content/88/3/1184.full.pdf>; Consumers Int'l, *Comments on the Discussion Paper of the Electronic Working Group on Issues Related to Standards Held at Step 8* (2012) (“[P]igs taking ractopamine were reported to have suffered adverse effects—hyperactivity, trembling, broken limbs, inability to walk and death.”); B.W. James et al., *Effect of Dietary L-Carnitine and Ractopamine-HCL (Paylean) on the Metabolic Response to Handling Growth-Finishing Pigs*, Swine Day 158, 158 & 164 (2004) (stating that “pigs fed Paylean are more susceptible to stress when handled aggressively, compared with pigs not fed Paylean” and take longer to return to normal).

<sup>10</sup> Wang et al., *supra* note 8, at 1248.

<sup>11</sup> New Animal Drugs for Use in Animal Feeds; Ractopamine Hydrochloride, 65 Fed. Reg. 4,111 (Jan. 26, 2000).

<sup>12</sup> See Office of New Animal Drug Evaluation, Ctr. for Veterinary Med., FDA, *Finding of No Significant Impact and Environmental Assessment, Optaflexx (Ractopamine HCl) Type A Medicated Article for Beef Cattle Feed 1* (2000).

FDA-approved uses for ractopamine are to increase weight gain, improve feed efficiency, and increase carcass leanness.<sup>13</sup> Elanco / Eli Lilly's names for this drug reflect the drug's effects: ractopamine is marketed as "Paylean" for swine, and "Optaflexx" and "Heifermax" for cattle. FDA has approved "continuous[]" ractopamine use for a specified period just prior to an animal's slaughter.<sup>14</sup> FDA regulations address both the amount of ractopamine permitted to be used in animal feed and the tolerance levels for ractopamine residue in meat.

Industrial animal food production operations use ractopamine in animal feed typically during the "finishing process" (typically days or weeks before slaughter, depending on the animal and drug dosage) to increase animal weight gain, improve feed efficiency, and increase meat leanness. Scientific studies and drug manufacturer estimates conclude that ractopamine use allows producers to increase their profits by as much as \$2 per head.<sup>15</sup>

Despite FDA's approval, evidence suggests that ractopamine may have seriously detrimental animal and human health effects, and compromise animal welfare.<sup>16</sup> Moreover, FDA's minimal review of the drug under the National Environmental Policy Act ("NEPA") may not have adequately evaluated the drug's environmental effects. FDA even issued a warning letter to Elanco Animal

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<sup>13</sup> 21 C.F.R. § 558.500(e)(1)(i).

<sup>14</sup> *See id.*

<sup>15</sup> Helena Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, NBCNEWS.com (Jan. 25, 2012), <http://www.nbcnews.com/business/dispute-over-drug-feed-limiting-us-meat-exports-174014>.

<sup>16</sup> For purposes of this Petition, "animal welfare" means protection against animal suffering. It recognizes that some animals, including pigs, cattle, and turkeys, have interests and are capable of experiencing pain and suffering. Animal welfare refers to a respect for such interests and capacities. The physical and behavioral changes in animals from ractopamine affect animal welfare. Cass Sustein & Martha Nussbaum eds., *Animal Rights: Current Debates and New Directions* 4-5 (Oxford Univ. Press 2004), available at <http://www.scribd.com/doc/63778967/Martha-Nussbaum-Animal-Rights-Current-Debates-and-New-Directions>.

Health/Eli Lilly in 2002 for failure to report “any unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or severity associated thereof.”<sup>17</sup> Subsequently, FDA approved ractopamine for use in cattle and turkeys.<sup>18</sup>

Ractopamine may be linked to acute toxicity, genotoxicity, cardiovascular changes, muscular skeletal tremors, and behavioral changes in animals.<sup>19</sup>

Ractopamine is also associated with “downer” or lame animals completely unable to walk, demonstrations of high stress levels, hyperactivity, trembling, broken limbs, and death.<sup>20</sup> High-stress animals exhibit behavioral problems and have difficulty socializing with other animals, resulting in more social hierarchy issues and fights within a flock or herd. Some reports indicate animals become so aggressive and hyperactive that they must be medicated to calm them down for shipping to

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<sup>17</sup> Letter from Gloria J. Dunnavan, Dir., Div. of Compliance, Ctr. for Veterinary Med., Office of Surveillance & Compliance, to Patrick C. James, President, Elanco Animal Health, A Div. of Eli Lilly & Co. 3 (Sept. 12, 2002).

<sup>18</sup> See New Animal Drugs; Ractopamine, 73 Fed. Reg. 72,714 (Dec. 1, 2008) (approving ractopamine for use in turkeys); New Animal Drugs; Ractopamine, 68 Fed. Reg. 54,658 (Sept. 18, 2003) (approving ractopamine for use in cattle). Similar to the approval for use in swine (65 Fed. Reg. 4,111 (Jan. 26, 2000)), in 2003, FDA concluded that an environmental impact statement was not required for use of ractopamine in cattle or turkeys. See Office of New Animal Drug Evaluation, Ctr. for Veterinary Med., U.S. Food & Drug Admin., *Finding of No Significant Impact, Optaflexx (Ractopamine HCl) Type A Medicated Article for Beef Cattle Feed* (2000); Office of New Animal Drug Evaluation, Ctr. for Veterinary Med., FDA, *Finding of No Significant Impact, Topmax (Ractopamine HCl) In the Feed of Turkeys* (2003).

<sup>19</sup> See, e.g., Ctr. for Veterinary Med., *Adverse Drug Effects Comprehensive Clinical Detail Listing 1/1/1987 thru 3/31/2011, Drug Listing: N thru S 177-84*, available at <http://web.archive.org/web/20110426003851/http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM055411.pdf> (last visited Dec. 17, 2012) (listing adverse drug effects for horses, pigs, cattle, turkeys, dogs, and humans).

<sup>20</sup> Consumers Int'l, *supra* note 9; B.W. James et al., *Effect of Dietary L-Carnitine and Ractopamine-HCL (Paylean) on the Metabolic Response to Handling Growth-Finishing Pigs*, Swine Day 158, 158 &164 (2004) (stating that “pigs fed Paylean are more susceptible to stress when handled aggressively, compared with pigs not fed Paylean” and take longer to return to normal); J.N. Marchant-Forde et al., *The Effects of Ractopamine on the Behavior and Physiology of Finishing Pigs*, 81 J. Animal Sci. 416, 416-17 (2003) (stating that animals on ractopamine have increased gait problems and behavioral reactivity and spend more time lying and less time walking).

slaughter.<sup>21</sup> “Downer” animals from drugs like ractopamine are not only inhumanely-treated animals, but also pose dangers to our food supply.<sup>22</sup> According to one study evaluating the effects of ractopamine on pigs, “[t]he occurrence of downer pigs may be amplified by the industry trend of producing a more heavily muscled, lean genotype pig.”<sup>23</sup> “Downer” pigs have increased cortisol levels, which results from stress caused by illness, trauma, or environmental changes.<sup>24</sup> The effect of “downer” animals in the food chain poses a risk to human health.<sup>25</sup>

Ractopamine residue in animal tissue has been linked to poisoning of humans.<sup>26</sup> For example, the Sichuan Pork Trade Chamber of Commerce in China estimates that between 1998 and 2010, 1,700 people were poisoned from eating Paylean pigs.<sup>27</sup> Studies recognize “there is a possibility that adulteration of feed with ractopamine could result in residues in animal tissues and lead to human poisoning.”<sup>28</sup>

Ractopamine is banned, restricted, or not allowed for use in animals and imported animal products in 160 nations namely China, Taiwan, and the 27 nations

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<sup>21</sup> See, e.g., D. Courtheyn et al., *Recent Developments in the Use and Abuse of Growth Promoters*, 473 *Analytic Chimica Acta* 71, 80 (2002).

<sup>22</sup> Lameness with difficulty walking due to Paylean does not translate into “lost” pigs as they may still be forced to slaughter and enter the food system. See, e.g., Comments from the Humane Society of the United States to Farm Sanctuary’s Petition to Condemn Other Non-Ambulatory Disabled Livestock at Slaughter, Docket ID No. FSIS-2010-0041, at 34 (April 8, 2011) (submitted concurrently with this petition) (hereinafter “HSUS Comments”); see also 76 Fed. Reg. 6,572 (Feb. 7, 2011).

<sup>23</sup> James et al., *supra* note 20, at 159.

<sup>24</sup> *Id.* at 165.

<sup>25</sup> HSUS Comments, *supra* note 22.

<sup>26</sup> Wang et al., *supra* note 8, at 1248.

<sup>27</sup> Martha Rosenberg, *Why Has the FDA Allowed a Drug Marked ‘Not Safe for Use in Humans’ to be Fed to Livestock Right Before Slaughter?*, AlterNet (Feb. 2, 2010), [http://www.alternet.org/story/145503/why\\_has\\_the\\_fda\\_allowed\\_a\\_drug\\_marked\\_'not\\_safe\\_for\\_use\\_in\\_humans'\\_to\\_be\\_fed\\_to\\_livestock\\_right\\_before\\_slaughter](http://www.alternet.org/story/145503/why_has_the_fda_allowed_a_drug_marked_'not_safe_for_use_in_humans'_to_be_fed_to_livestock_right_before_slaughter).

<sup>28</sup> Wang et al.; *supra* note 8, at 1248.

of the European Union (“EU”).<sup>29</sup> Additionally, Russia recently announced it would not import meat that contained ractopamine residues and that was not certified ractopamine-free.<sup>30</sup> Despite international condemnation of the drug, the U.S. continues to pervasively feed ractopamine to our food-producing animals. It estimated that ractopamine is administered to 60 to 80 percent of U.S. pigs alone.<sup>31</sup>

Furthermore, despite strict standards or bans in most of the world following years of scientific and political stalemate, in 2012 the United Nations international food standards body, Codex Alimentarius Commission, adopted a maximum residue limit (“MRL”) for ractopamine that is less strict than those of Europe, China, Taiwan, and many other nations.<sup>32</sup> While Codex tolerance levels are insufficient to protect human and animal health, and less protective than an outright ban, they are still more stringent than current U.S. standards:

	<b>FDA Tolerance Levels<sup>33</sup></b>	<b>Codex Tolerance Levels</b>
Acceptable Daily Intake (human)	1.25 ppb of body weight per day	0-1 ppb of body weight per day
Cattle Muscle	30 ppb	10 ppb
Cattle Liver	90 ppb	40 ppb
Pig Muscle	50 ppb	10 ppb
Pig Liver	150 ppb	40 ppb
Turkey Muscle	100 ppb	None established
Turkey Liver	450 ppb	None established

<sup>29</sup> See, e.g., Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, *supra* note 15; Council Directive 96/22, 1995 O.J. (L 125) 3 (EC), available at [http://ec.europa.eu/food/food/chemicalsafety/residues/council\\_directive\\_96\\_22ec.pdf](http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_22ec.pdf) (banning ractopamine in the European Union); see World Health Org., WHO Drug Information Vol. 14, No. 2000, <http://apps.who.int/medicinedocs/en/d/Jh1463e/8.2.html>.

<sup>30</sup> *Russia Throws Poisonous Meat Back to US*, Pravda, Dec. 11, 2012, [http://english.pravda.ru/business/companies/11-12-2012/123129-russia\\_usa\\_meat\\_imports-0/](http://english.pravda.ru/business/companies/11-12-2012/123129-russia_usa_meat_imports-0/).

<sup>31</sup> Bottemiller, *supra* note 15.

<sup>32</sup> Codex Alimentarius Comm’n, *Maximum Residue Limits (MRLs) for Veterinary Drugs in Foods*, at 32 (July 2012), available at [http://www.codexalimentarius.net/vetdrugs/data/MRL2\\_e\\_2012.pdf](http://www.codexalimentarius.net/vetdrugs/data/MRL2_e_2012.pdf) (adopting standards for ractopamine).

<sup>33</sup> 21 C.F.R. § 556.570.

For the reasons discussed below and as supported by the materials in the record, Petitioners request FDA to: immediately undertake its required review of Codex standards; publish this Petition and allow public comment on it; undertake comprehensive studies of the effects of ractopamine on food-producing animals as well as humans and the environment; and, during the pendency of this review and study, significantly strengthen U.S. standards by deviating from Codex Standards and set human and animal health and welfare-based standards or, at a minimum, temporarily meet existing Codex standards.

### **PETITIONERS**

The **Animal Legal Defense Fund** (“ALDF”) is a nonprofit organization located at 170 East Cotati Avenue, Cotati, CA 94931. Established in 1979, ALDF works to promote stronger enforcement of animal anti-cruelty laws and more humane treatment of animals in every corner of American life. ALDF protects animals through litigation, legal assistance to prosecutors, strengthening legislation, and student education.

The **Center for Food Safety** (CFS) is a nonprofit organization located at 660 Pennsylvania Avenue, S.E., Washington D.C. 20003. Established in 1997, CFS works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS conducts litigation, advocacy, education, and grassroots organizing to fulfill its organizational goals.

### **STATEMENT OF THE LAW**

**Federal Food, Drug, and Cosmetic Act** (“FFDCA”), 21 U.S.C. § 301 *et seq.* and relevant regulations: (*in pertinent part*)

- FFDCA Generally:

The FFDCA and accompanying regulations govern the use of all new animal drugs (“NADs”).<sup>34</sup> The primary purpose of the FFDCA is to protect consumer health and safety.<sup>35</sup> The FFDCA is also intended to protect animal health.<sup>36</sup> FDA’s Congressionally-mandated mission is to “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner” and to protect the public health by ensuring that “foods are safe, wholesome, sanitary, and properly labeled.”<sup>37</sup> The statute requires a precautionary approach to the safety of food, drugs, devices, and cosmetics (e.g., substances which *may* render a food injurious to health shall be deemed to be adulterated under 21 U.S.C. § 342). The FFDCA instructs the Secretary to promulgate regulations that will “promote honesty and fair dealing in the interest of consumers” whenever his judgment allows him to conclude that such an action will meet the goal of the statute.<sup>38</sup> Grounds for approving and revoking new animal drug applications include is a determination “whether such drug is safe for use,”<sup>39</sup> and the agency “shall consider . . . the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance.”<sup>40</sup>

- FDA must consider Codex:

“All food standards adopted by the Codex Alimentarius Commission will be reviewed” and “will be accepted without change, accepted with change, or not accepted.”<sup>41</sup>

- Request for studies:

“A proposal to require additional or continued studies with a drug for which a new drug application has been approved may be made by the Commissioner on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter. Prior to issuance of such a

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<sup>34</sup> See 21 U.S.C. § 360b.

<sup>35</sup> See generally FDA, *Legislation* (last updated July 9, 2012), <http://www.fda.gov/regulatoryinformation/legislation/default.htm>.

<sup>36</sup> See, e.g., FDA, *FDA’s Response to Public Comments* (last updated Nov. 8, 2012), <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113612.htm> (“FDA’s authority over new animal drugs includes review of the effects of such drugs on the health of the animals. To the extent that animal welfare encompasses animal health, FDA does include such issues in its review.”).

<sup>37</sup> 21 U.S.C. § 393(b)(1), (2)(A).

<sup>38</sup> See 21 U.S.C. § 341.

<sup>39</sup> 21 U.S.C. § 360b(d)(1)(D).

<sup>40</sup> 21 U.S.C. § 360b(d)(2)(B).

<sup>41</sup> 21 C.F.R. § 130.6(a).

proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. All requirements for special studies, records, and reports will be published in § 310.304.”<sup>42</sup>

And more broadly, under 21 C.F.R. § 10.25(a), “[a]n interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.”

Administrative Procedure Act (“APA”), 5 U.S.C. § 500 et seq.

- The APA standard applies to FDA’s decisions under the FFDCA. The applicable standard is whether the agency’s decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.<sup>43</sup> As the U.S. Supreme Court has stated:

Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.<sup>44</sup>

- In general, agency decisions “that [are] inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute” are impermissible.<sup>45</sup>
- Under the APA, agencies are required to “give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”<sup>46</sup>

### **SUMMARY OF ARGUMENT**

Compared to widely-applied international standards such as bans, the Codex standard is not the most protective standard for ractopamine. Under the FFDCA

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<sup>42</sup> 21 C.F.R. § 310.303(b).

<sup>43</sup> 5 U.S.C. § 706(2)(A); see *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2010).

<sup>44</sup> *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>45</sup> See *Ocean Advocates v. U.S. Army Corps of Eng’rs*, 402 F.3d 846, 858-59 (9th Cir. 2005) (internal citation omitted).

<sup>46</sup> 5 U.S.C. § 553(e).

framework, and unlike the Codex standard, consumer and animal health must trump merchants' wishes. However, under the FFDCA, FDA is required to review Codex standards, and Codex standards for ractopamine are currently more stringent than the FDA's regulations. Furthermore, existing scientific studies are wholly inadequate to justify continued use of ractopamine, or to protect human health, animal welfare, and the environment from the effects of ractopamine use at current approved levels. FDA must undertake comprehensive health- and welfare-based scientific studies, and its failure or refusal to do so is contrary to the FFDCA and the APA. Under the FFDCA, FDA's only purpose is to protect human health. In the meantime, while FDA reviews Codex standards and performs studies, the agency should significantly strengthen our nation's ractopamine standards by setting the most stringent standards possible, taking into consideration human health and animal welfare based standards, as well as the more stringent bans and restrictions employed by most of the world. If FDA determines it will not or cannot deviate from the Codex standards to set more health- and welfare-based standards, it should at least follow Codex standards while it undertakes a review of other nations' approaches and conducts comprehensive scientific studies. Any other action is contrary to the FFDCA and the APA.

### **STATEMENT OF FACTUAL GROUNDS**

#### **I. U.S. STANDARDS FOR RACTOPAMINE ARE AMONG THE MOST LENIENT IN THE WORLD**

The U.S. has some of the most lenient ractopamine standards in the world, putting animals, humans, and the environment at risk. Approximately 160 nations and treaty bodies—including the EU, China, and Taiwan—have banned or restricted

both the use of ractopamine and the import of certain products containing ractopamine residues. In December 2012, Russia announced it would no longer accept meat products that tested positive for ractopamine and were not certified ractopamine-free.<sup>47</sup> Unlike other countries, the U.S. Department of Agriculture (“USDA”) does not have a strong testing and certification program in place for ractopamine.<sup>48</sup> USDA’s Food Safety and Inspection Service (“FSIS”) has done little sampling. In 2010, USDA did no tests on 22 billion pounds of pork, and only tested 712 samples from 26 billion pounds of beef.<sup>49</sup> Even then, USDA has not yet released the results of these tests.

## **II. CODEX STANDARDS DO NOT OFFER SUFFICIENT ANIMAL WELFARE AND HUMAN HEALTH PROTECTIONS**

Codex’s 2012 MRLs for ractopamine do not offer sufficient animal welfare and public health protections.

First, the vote to advance MRLs at Codex only passed by one vote of the members present—a rarity for Codex.<sup>50</sup> Such a close vote is an indication of the lack of support for the MRLs within Codex itself.

Second, Codex’s accepted methodology of the Joint Food & Agriculture Organization / World Health Organization Expert Committee of Food Additives

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<sup>47</sup> *Russia Throws Poisonous Meat Back to US*, *supra* note 30.

<sup>48</sup> The EU and Russia require exporters to certify their meat is ractopamine-free. Helena Bottemiller, *U.S. and Russia Spar Over Ractopamine in Pork and Beef*, Food Safety News, Dec. 18, 2012, available at <http://www.foodsafetynews.com/2012/12/u-s-and-russia-spar-over-ractopamine-in-pork-and-beef/>. Taiwan also tests for ractopamine. Helena Bottemiller, *U.S. Presses Taiwan on Ractopamine Ban*, Food Safety News, Feb. 7, 2012, available at <http://www.foodsafetynews.com/2012/02/us-presses-taiwan-on-ractopamine-ban/>.

<sup>49</sup> See, e.g., Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, *supra* note 15.

<sup>50</sup> See Helena Bottemiller, *Codex Adopts Ractopamine Limits for Beef and Pork*, Food Safety News (July 6, 2012), <http://www.foodsafetynews.com/2012/07/codex-votes-69-67-to-advance-ractopamine-limits-for-beef-and-pork/#.UM-yaKX758s>.

(“JECFA”) to calculate the acceptable daily intake (“ADI”) for ractopamine is flawed. The EU Food Safety Authority and Consumers International have categorized JECFA’s methodology as experimentally weak, uncertain, and providing limited conclusiveness.<sup>51</sup> Some of the telling critiques of the study Codex adopted include, for example:

- JECFA used a human study in connection with its analysis of ractopamine, but the study was based on an incredibly insufficient sample size from which to draw reliable conclusions. The study involved only six young, healthy males—one of whom withdrew after suffering from sensations of increased heart rate and heart pounding—with an average age of 23.5 years, and the study did not account for high-risk subpopulations such as pregnant women and the elderly.<sup>52</sup> The small sample size of the study is an insufficient basis for Codex to justifiably determine the 2012 ractopamine MRLs.
- JECFA relied on data from different species (dog, monkey, rodent, and human) of differing degrees of sensitivity to ractopamine. The dog was the most sensitive and the monkey the least sensitive. Instead of using the most sensitive species to establish a no observable adverse effect level (“NOAEL”) and set a protective standard for humans, the study set a standard for humans based on the least sensitive monkey.<sup>53</sup>
- JECFA’s study was not designed to be a basis for defining a “no effect” level of ractopamine. It was only designed to establish dose-effect responses to enable suitable doses to then be selected for a larger double-blind study.<sup>54</sup>
- JECFA’s study was restricted to the cardiovascular effects of ractopamine and did not cover all the effects that could be expected.<sup>55</sup> Of the cardiovascular parameters evaluated, many of the factors evaluated were secondary effect;<sup>56</sup>

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<sup>51</sup> See *Safety Evaluation of Ractopamine, Scientific Opinion of the Panel on Additives and Products or Substances Used in Animal Feed*, 7 Euro. Food Safety Auth. J., at 18 (April 2009) [hereinafter *Safety Evaluation of Ractopamine*].

<sup>52</sup> See *id.* at 17-18 (April 2009)

<sup>53</sup> See, e.g., *id.* at 9.

<sup>54</sup> See *id.* at 18.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

- The information relied upon by Codex does not adequately account for species distinctions or genetic differences within a population.<sup>57</sup>

Lastly, in making its MRL decision, Codex did not obtain more recent data for its conclusions about consumer safety, but used previously-submitted studies provided by drug notifiers, and pooled study results.<sup>58</sup> As a result, the EU Food Safety Authority's analysis concluded that the Codex acceptable daily intake ("ADI") levels could not be supported, and no proposal for MRLs could be made.<sup>59</sup> Based on the above, the JECFA study and Codex's ractopamine standards are flawed. Furthermore, their complete failure to evaluate animal welfare and to use the strictest human health protections available should be discounted by FDA during its review of Codex standards as inconsistent with the FFDCa and the APA.

### **III. EVIDENCE DEMONSTRATES ADVERSE EFFECTS OF RACTOPAMINE ON ANIMALS AND HUMANS; ADDITIONAL AND MORE COMPREHENSIVE SCIENTIFIC STUDY IS REQUIRED**

Ractopamine residues are found in food samples, and ractopamine adverse drug events occur at shockingly high rates. For example, just recently one test found that one-fifth of 240 products tested contained ractopamine.<sup>60</sup> In the 12 years since its approval, evidence demonstrating ractopamine's risks to animals and humans has grown. FDA data indicates that more than 218,000 animals have experienced adverse effects from the drug.<sup>61</sup> In March 2012, FDA stated to media that it had

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<sup>57</sup> See *Safety Evaluation of Ractopamine*, *supra* note 51, at 26 (stating that "specific ratios free ractopamine vs. total residues (in liver and kidneys) for pig and cattle should have been derived and used instead of common ratios for both species").

<sup>58</sup> *Id.* at 25.

<sup>59</sup> *Id.* at 27-28

<sup>60</sup> *What's in That Pork?*, Consumer Reports, Jan. 2013, available at <http://www.consumerreports.org/cro/pork0113.htm>.

<sup>61</sup> Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, *supra* note 15.

looked at the adverse drug event (“ADE”) reports for ractopamine and, after excluding reports of ineffectiveness, meat abnormalities, and fertility abnormalities, the number of animals with ADE reports associated with ractopamine was reduced to 160,917.<sup>62</sup> FDA has also issued ADE reports for ractopamine in humans; the reports identify 23 different types of negative medical symptoms in humans believed to be caused by the drug.<sup>63</sup> Additionally, since FDA approved ractopamine in 2000, several studies have been published indicating potential animal and human health risks, warranting further and more comprehensive scientific study. Moreover, FDA’s own information points to significant problems with ractopamine use.<sup>64</sup> FDA’s data demonstrates more pigs have experienced adverse effects from ractopamine than any other veterinary drug.<sup>65</sup>

Furthermore, existing scientific studies on ractopamine are inadequate to analyze the impacts of the above information on animal welfare, human health, and the environment. Therefore there is currently a lack of reliable information upon which to base continued FDA approval of ractopamine. Flaws with existing studies to our knowledge include, *inter alia*:

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<sup>62</sup> Gretchen Goetz, *Animal Drug Widely Used in US Meat the Focus of Trade Dispute*, Food Safety News (Jan. 26, 2012), [http://www.foodsafetynews.com/2012/01/a-controversial-animal-drug-banned/#.UM\\_C36X758s](http://www.foodsafetynews.com/2012/01/a-controversial-animal-drug-banned/#.UM_C36X758s).

<sup>63</sup> Ctr. for Veterinary Med., Ctr. for Veterinary Med., *Adverse Drug Effects Comprehensive Clinical Detail Listing 1/1/1987 thru 3/31/2011*, Drug Listing: N thru S 177-84, *supra* note 19, at 177, 182-83.

<sup>64</sup> See, e.g., Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, *supra* note 15; see also Bottemiller, *Codex Adopts Ractopamine Limits for Beef and Pork*, *supra* note 50.

<sup>65</sup> Helena Bottemiller, *Ractopamine and Pigs: Looking at the Numbers*, Food & Env’t Reporting Network (Feb. 23, 2012), <http://thefern.org/2012/02/ractopamine-and-pigs-looking-at-the-numbers/> (noting the next highest number after 218,116 pigs negatively affected by ractopamine was significantly lower: 32,738 pigs negatively affected by Tylosin).

- Comparing hydrochloride products solely for the economic evaluation of animal growth performance, carcass characteristics, and beef shear force;<sup>66</sup>
- Exclusion of “exotic” breeds.<sup>67</sup>
- Failure to account for genetic differences within a population. For example, studies FDA used to determine MRLs for ractopamine were based on rhesus monkeys, rather than other species or even a human study.<sup>68</sup>
- Use of small samples, as in the testing of categories such as beef shear force.<sup>69</sup>
- Lack of understanding as to the mechanics of how ractopamine works as it does.<sup>70</sup>
- Lack of methods for detecting ractopamine in animal feeds that are fast, sensitive or economical, and lack of assays that exist for this purpose.<sup>71</sup>

To truly understand the drug’s effects on animals and humans and analyze tolerance levels (not just effectiveness levels), FDA must immediately undertake comprehensive studies.

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<sup>66</sup> See J. Van Donkersgoed et al., *Comparative Effects of Zilpaterol Hydrochloride and Ractopamine Hydrochloride on Growth Performance, Carcass Characteristics and Longissimus Tenderness of Feedlot Heifers Fed Barley-Based Diets*, 27 *The Prof'l Animal Scientist* 116, 117 (2011), available at <http://pas.fass.org/content/27/2/116.full.pdf+html>.

<sup>67</sup> See *id.*

<sup>68</sup> See FDA Freedom of Information Summary: *Original New Drug Application NADA 140-863, Ractopamine hydrochloride (Paylean)* (1999), [http://consumer.fda.gov.tw/Files/doc/US%20FDA%20\(evaluation%20of%20ractopamine%20for%20swine\).pdf](http://consumer.fda.gov.tw/Files/doc/US%20FDA%20(evaluation%20of%20ractopamine%20for%20swine).pdf); see also Letter from Michael Hansen, Senior Scientist, and Urvashi Rangan, Director of Consumer Safety and Sustainability, Consumers Union, to Margaret Hamburg, Commissioner of FDA (Dec. 4, 2012), [http://www.consumersunion.org/pdf/FDA\\_Stop\\_Use\\_of\\_Ractopamineractopamine\\_1212.pdf](http://www.consumersunion.org/pdf/FDA_Stop_Use_of_Ractopamineractopamine_1212.pdf).

<sup>69</sup> See J. Van Donkersgoed et al., *supra* note 66.

<sup>70</sup> See generally N.W. Shappell et al., *Response of C2C12 Mouse and Turkey Skeletal Muscle Cells to the Beta-adrenergic Agonist Ractopamine*, 78 *J. Anim. Sci.* 699 (2000).

<sup>71</sup> Wang et al., *supra* note 8.

#### **IV. CONSUMERS ARE CONCERNED WITH THE USE OF DRUGS IN ANIMAL FEED SUCH AS RACTOPAMINE**

Surveys indicate that the majority of U.S. consumers are very concerned about the issues central to this Petition. For example, a majority of consumers consider the well-being of farm animals in purchasing meat, believe that the well-being of farm animals is more important than low meat prices, and believe the government should take an active role in promoting animal welfare.<sup>72</sup> Nearly 70 percent of consumers want to know more about the ways farmers ensure animal care,<sup>73</sup> 92 percent of consumers agree it is important to consumers that farm animals are well cared for, and 85 percent of consumers agree that even if a farm animal is used for meat the quality of an animal's life is still important.<sup>74</sup> Consumers are also in favor of labeling animal welfare labeling that indicates whether products are, for example, produced from farms using gestation crates/stalls or using battery cages.<sup>75</sup> Consumers support government regulation and laws that protect farm animals from cruelty and abuse.<sup>76</sup>

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<sup>72</sup> See, e.g., Robert W. Prickett, F. Bailey Norwood, & Jayson L. Lusk, *Consumer Preferences for Farm Animal Welfare: Results from a Telephone Survey of U.S. Households*, available at <http://asp.okstate.edu/baileynorwood/Survey4/files/Robspaper.pdf> (last visited Dec. 17, 2012).

<sup>73</sup> Demeter Commc'ns, *What 'Indicator Consumers' Want to Know Most About How U.S. Foods Are Produced* (2010), available at <http://demetercommunications.com/wp-content/uploads/2010/04/REVFINAL.SegmenTrakExecSummary.4.28.10.pdf>.

<sup>74</sup> Andrew Rauch & Jeff S. Sharp, Ohio State Univ., *Ohioans' Attitudes About Animal Welfare* (2005), available at [http://ohiosurvey.osu.edu/pdf/2004\\_Animal\\_report.pdf](http://ohiosurvey.osu.edu/pdf/2004_Animal_report.pdf).

<sup>75</sup> See, e.g., Glynn T. Tonsor & Christopher A. Wolf, Kansas State Univ., *Mandatory Labeling of Animal Welfare Attributes: Public Support and Considerations for Policymakers 2* (2011), available at [http://www.agmanager.info/livestock/marketing/animalwelfare/AW-Labeling\\_FactSheet\\_07-19-11.pdf](http://www.agmanager.info/livestock/marketing/animalwelfare/AW-Labeling_FactSheet_07-19-11.pdf).

<sup>76</sup> See Joseph Zogby, Zogby Int'l, *Nationwide Views on the Treatment of Farm Animals* (2003), available at <http://civileats.com/wp-content/uploads/2009/09/AWT-final-poll-report-10-22.pdf>.

Ractopamine affects animal welfare, and animal welfare is a concern of many consumers.<sup>77</sup> Ractopamine is associated with cardiovascular problems, muscular skeletal lameness, and high stress levels in animals. Ractopamine changes animal behaviors, which in turn alter animal social hierarchical structures. Tumult in social dynamics can cause great stress for animals.<sup>78</sup> Studies of ractopamine's effects on humans are very limited, but they do demonstrate effects such as elevated heart rate and the sensation of heart pounding.<sup>79</sup> Ractopamine may have additional effects on animals and humans such as toxicity, genotoxicity, behavioral changes, and reproductive and endocrinological problems.<sup>80</sup>

More generally, it is clear that consumers are developing an awareness of drugs in their food, and use of drugs in food-producing animals. For example, consumers are "very concerned" about the use of antimicrobials in livestock feed, antimicrobial residue in meat products for human consumption, and environmental pollution from antimicrobial use.<sup>81</sup> By analogy consumers would arguably be concerned about the toxicity and exposure effects of ractopamine if they were more

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<sup>77</sup> See Demeter Commc'ns, *supra* note 73 (reporting that almost 70 percent of consumers want to know ways farmers ensure animal care); Rauch & Sharp, *supra* note 74 (reporting that consumers agree that farm animal care and the quality of the animals' lives are important factors).

<sup>78</sup> Helena Bottemiller, Food & Env't Reporting Network, *Ractopamine and Pigs: Looking at the Numbers*, *supra* note 65; see also A. Kittawornrat and J. Zimmerman, *Toward a Better Understanding of Pig Behavior and Pig Welfare*, *Animal Health Research Reviews*, Oct. 18, 2010, at 4 ("In principle, welfare issues arise in pig production when there is a mismatch between a pig's instincts and its environment. That is, behavioral impulses may be expressed inappropriately when instinctual behavior is thwarted.")

<sup>79</sup> See *Safety Evaluation of Ractopamine*, *supra* note 51, at 19.

<sup>80</sup> See, e.g., *id.* (addressing cardiovascular effects). Studies have not eliminated the possibility that effects of ractopamine noted in laboratory animals, or not yet studied in laboratory animals, do not occur in humans. Thus, there is the possibility that ractopamine causes these effects in humans.

<sup>81</sup> See *Meat on Drugs*, Consumer Reports (2012), available at [http://notinmyfood.org/wordpress/wp-content/uploads/2012/06/CR\\_Meat\\_On\\_Drugs\\_Report\\_06-12.pdf](http://notinmyfood.org/wordpress/wp-content/uploads/2012/06/CR_Meat_On_Drugs_Report_06-12.pdf); *U.S. Public's Awareness and Perceptions of Antibiotic Use in Food Animal Production*, Applegate (2011); see also David S. Conner, Victoria Campbell-Arvai, & Michael W. Hamm, *Consumer Preferences for Pasture-Raised Animal Products: Results from Michigan*, 39 *J. of Food Distribution Research* 12 (2008).

aware of its widespread use in the U.S. meat industry and the lack of scientific basis for the drug's original and continued FDA approval.

## **STATEMENT OF LEGAL GROUNDS**

### **I. FDA IS REQUIRED TO REVIEW CODEX ALIMENTARIUS STANDARDS**

The Codex Commission “adopts recommended standards for food products which member countries are then *obliged* to consider for adoption.”<sup>82</sup> As a member of the Commission, the U.S. is bound to consider Codex standards for adoption.<sup>83</sup> In enacting the FFDCA, Congress intended for that there be an ongoing relationship between FDA and international food standard bodies. For example, 21 U.S.C. §§ 360b(a)(6) and (b)(1) allow the Secretary to consider Codex standards, among other factors, in establishing, evaluating, or revoking new animal drug tolerance levels. A similar process exists for U.S. Environmental Protection Agency (“EPA”)’s determination of pesticide tolerances.<sup>84</sup> Moreover, FDA’s own regulations require it to review all food standards adopted by Codex. Under 21 C.F.R. § 130.6, “[a]ll food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration.” (emphasis added).

### **II. FDA MUST PROTECT HUMAN HEALTH, ANIMAL WELFARE, AND THE ENVIRONMENT BY STRENGTHENING RACTOPAMINE STANDARDS**

#### **A. FDA’s Obligation to Consumer Health Demands Stronger Ractopamine Standards**

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<sup>82</sup> *Pineapple Growers Ass’n of Haw. v. Food & Drug Admin.*, 673 F.2d 1083, 1084 (9th Cir. 1982) (emphasis added) (citing 37 Fed. Reg. 21102 (Oct. 5, 1972)).

<sup>83</sup> *Id.*

<sup>84</sup> “If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.” See 21 U.S.C. § 346a(b)(4).

Under the FFDCA, FDA is charged with upholding and enforcing the primary purpose of the Act, which is to protect consumer health and safety.<sup>85</sup> The FFDCA “was not designed primarily for the protection of merchants and traders; but was intended to protect the consuming public.”<sup>86</sup> FDA’s statutorily-prescribed mission is to “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner” and to protect the public health by ensuring that “foods are safe, wholesome, sanitary, and properly labeled.”<sup>87</sup> The statute requires a *precautionary* approach to the safety of food, drugs, devices and cosmetics (e.g., substances which *may* render a food injurious to health shall be deemed to be adulterated under 21 U.S.C. § 342). This precautionary approach is also wholly consistent with FDA’s Animal Feed Safety System, including the Fourth Draft of the Framework of the FDA Animal Feed Safety System and the principles put forth by FDA in its Food Protection Plan (prevention, intervention, and response).<sup>88</sup> Moreover, federal courts have recognized that the FFDCA provides a “comprehensive scheme to protect the public from [animal] drugs that *may* be unsafe. . . .”<sup>89</sup> “[T]he very purpose of the [Federal Meat Inspection Act] and the FFDCA . . . is to ensure the safety of the nation’s food supply and to minimize the risk to public health from

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<sup>85</sup> 21 U.S.C. § 393(b); see *United States v. Lane Labs-USA*, 427 F.3d 219, 226-27 (3rd Cir. 2005).

<sup>86</sup> *United States v. Two Bags, Poppy Seeds*, 147 F.2d 123, 127 (6th Cir. 1945).

<sup>87</sup> 21 U.S.C. § 393(b)(1)-(2).

<sup>88</sup> See FDA, *Fourth Draft: Framework of the FDA Animal Feed Safety System* (2010), available at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/ucm196795.htm>; FDA, *Overview of FDA Animal Feed Safety System* (undated), <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/UCM277673.pdf>; FDA, *Fact Sheet: Food Protection Plan* (2007), available at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132705.htm> (promoting a preventative food and feed safety program, which requires consideration of all feed at all stages of production that could cause feed to be unsafe).

<sup>89</sup> *ALDF v. Promivi Veal Corp.*, 626 F.Supp. 278, 282 (D. Mass. 1986) (emphasis added).

potentially dangerous food and drug products.”<sup>90</sup> NADs such as ractopamine are not exempt from FDA’s obligations to the public, to animals, and to the environment. Where drugs *may* put the public at risk, FDA must remedy that failing.

With respect to NAD procedures, FDA requires demonstration by a NAD’s sponsor that the drug will lead to food products that are “safe for human consumption, that the drug is safe and effective for the animals in question, and that the manufacture and use of the drug will not harm the environment.”<sup>91</sup> Section 360b establishes procedures pursuant to which FDA may set residue tolerance levels for NADs, exempting the drug or edible portions of animals containing such residues from being “unsafe” under the FFDCa.<sup>92</sup> Drugs are either “safe and effective for use” or adulterated.<sup>93</sup> Adulterated drugs are not permitted under the FFDCa; the Act prohibits their introduction into interstate commerce.<sup>94</sup> In setting residue tolerances, FDA may “consider and rely on data . . . [available from] the Codex Alimentarius Commission,” and may even “revoke a tolerance . . . if scientific evidence shows the tolerance to be unsafe.”<sup>95</sup> Information shows that FDA’s current tolerance and residue levels insufficiently account for animal health problems and may be unsafe for consumers. Thus, U.S. ractopamine standards should be viewed as unsafe; studies should be performed that consider human and animal health,

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<sup>90</sup> *Baur v. Veneman*, 352 F.3d 625, 634-35 (2d Cir. 2003).

<sup>91</sup> *See, e.g., Stauber v. Shalala*, 895 F.Supp. 1178, 1190 (W.D. Wis. 1995); *see also* 21 U.S.C. §§ 321(u), 360b; *generally* 21 C.F.R. §§ 514.1(b)(8), 514.111(a)(4).

<sup>92</sup> 21 U.S.C. § 360b(a)(6).

<sup>93</sup> 21 U.S.C. §§ 360b(a)(6), (b)(1).

<sup>94</sup> 21 U.S.C. § 342(a)(2)(B)(ii) (unsafe NADs are “adulterated” under the FFDCa); 21 U.S.C. § 331 (prohibiting introduction of adulterated food into interstate commerce).

<sup>95</sup> 21 U.S.C. § 360b(a)(6).

animal welfare, and the environment, and more stringent standards put forth to reflect these considerations.

### **B. Labels Cannot Protect Consumers**

FDA's NAD labeling requirements for ractopamine cannot protect consumers. Certain FDA labels for medicated animal feed require statements such that ractopamine is not to be used on "animals intended for breeding."<sup>96</sup> In fact, if some of the ractopamine labels remained as they were originally issued, consumers would know more about the drug than the labels currently reveal. For example, the label *used* to say that pigs treated with Paylean were at an "increased risk for exhibiting the downer pig syndrome."<sup>97</sup> Now, ractopamine just simply "may increase the number of injured and/or fatigued pigs during marketing."<sup>98</sup> Also, ractopamine residues below the threshold amount are considered "incidental" food additives.<sup>99</sup> Without adequate studies, however, it is incomprehensible how FDA can conclude that certain amounts of ractopamine are "incidental."

### **C. FFDCFA Protects Food-Producing Animals**

In mandating FDA to "promote honesty and fair dealing in the interest of consumers," Congress declared that a central mission of the mandate is to protect public health.<sup>100</sup> To accomplish this mission, the FFDCFA "ensure[s] that any product regulated by the FDA is 'safe' and 'effective' for its intended use."<sup>101</sup> The FFCCA also

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<sup>96</sup> 21 C.F.R. § 558.500(d)(1).

<sup>97</sup> New Animal Drugs for Use in Animal Feeds; Ractopamine and Tylosin, 67 Fed. Reg. 71,820 (Dec. 3, 2002) (codified at 21 C.F.R. § 558.500(d)(1)(i)).

<sup>98</sup> 21 C.F.R. § 558.500(d)(2)(ii).

<sup>99</sup> See 21 C.F.R. § 501.100(a)(3).

<sup>100</sup> *Lane Labs-USA, Inc.*, 427 F.3d at 226-27; see also 21 U.S.C. § 393(b)(2).

<sup>101</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *id.* at 134 ("If the FDA discovers after approval that a drug is unsafe or ineffective, it 'shall, after due notice and opportunity

includes protection of animal health in certain contexts, namely in evaluating the safety of a NAD.<sup>102</sup>

First, pursuant to the FFDCFA, Congress authorized FDA to prohibit introduction or delivery into interstate commerce, or the manufacture of “any food... that is adulterated or misbranded.”<sup>103</sup> With regard to veterinary drugs provided to animals for human consumption, “a food shall be deemed to be adulterated . . . if it is or if it bears or contains . . . a new animal drug (or conversion product thereof) that is unsafe within the meaning of section [360b].”<sup>104</sup> Second, safety determinations for NADs require FDA to evaluate *both* human and animal health. “The term ‘safe,’ as used in ... sections 409, 512 [§ 360b], 571, 721, has reference to the health of man *or animal*.”<sup>105</sup> The text of section 360b also underscores Congressional concern for the health of the target animals. Grounds for approving and revoking NAD applications is a determination “whether such drug is safe for use,” and the agency “shall consider... the cumulative effect on man *or animal* of such drug, taking into account any chemically or pharmacologically related substance.”<sup>106</sup>

Third, FDA itself has concluded that Congress made animal health central to the NAD approval analysis.<sup>107</sup> FDA’s animal drug approval process requires both an

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for hearing to the applicant, withdraw approval’ of the drug.”); *see also* *Labs-USA, Inc.*, 427 F.3d at 226 (recognizing that “protecting consumer health and safety is a primary purpose of the FDCA”); *accord* 21 U.S.C. § 393(b)(2).

<sup>102</sup> New animal drug safety evaluations must consider animal health. *See* 21 U.S.C. §§ 321(u), 360b(d)(2)(B).

<sup>103</sup> *See* 21 U.S.C. § 331(a)-(d), (g), (m).

<sup>104</sup> 21 U.S.C. § 342(a)(2)(B)(ii).

<sup>105</sup> 21 U.S.C. § 321(u) (2012) (emphasis added).

<sup>106</sup> 21 U.S.C. § 360b(d)(2)(B) (emphasis added); *see also* *Stauber*, 895 F. Supp. at 1191 (citing animal health as a factor for FDA determination of animal drug safety).

<sup>107</sup> *See, e.g.*, *Enrofloxacin for Poultry*, 65 Fed. Reg. 64,954 (Oct. 31, 2000) (“Accordingly, CVM must consider not only safety of the new animal drug to the target animal but also safety to humans of substances formed in or on food as a result of the use of the new animal drug.”).

evaluation of the cumulative effect on animals and an assurance that the drug does not adversely effect the treated animal.<sup>108</sup>

### **III. FDA MUST PROMOTE HONESTY AND FAIR DEALING IN THE INTEREST OF CONSUMERS; THUS FDA MUST STUDY AND STRENGTHEN RACTOPAMINE STANDARDS**

Section 401 of the FFDCA, which provides statutory authority for 21 C.F.R. § 130.6, instructs the Secretary to promulgate regulations that will “promote honesty and fair dealing in the interest of consumers” whenever his judgment allows him to conclude that such an action will meet the goal of the statute.<sup>109</sup> FDA regulations recognize Codex standards should be considered in evaluating whether honesty and fair dealing are being promoted.<sup>110</sup> In the case of ractopamine, there are now at least 3 different levels of protection for animals, humans, and the environment: nations such as the U.S., with tolerance levels more liberal than Codex; Codex standards; and nations that have restricted or banned ractopamine. The U.S. Supreme Court has held that a diversity of standards “would tend to confuse and mislead consumers ... and would impede rather than promote honesty and fair dealing in the interest of consumers.”<sup>111</sup> Similarly, with varying ractopamine standards, FDA must conclude that action is necessary on this issue to promote honesty and fair dealing in the interest of consumers.

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<sup>108</sup>See FDA, “Overview of the Animal Drug Approval Process,” available at <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/FrequentlyAskedQuestions/UCM047138.pdf>.

<sup>109</sup> 21 U.S.C. § 341.

<sup>110</sup> See 21 C.F.R. § 130.5(b) (“Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.”); see also Letter from Donald W. Kraemer, Acting Deputy Director for Operations, Ctr. for Food Safety & Applied Nutrition, to Kristen C. Gunter (Oct. 2011) (denying a petition to adopt a Codex standard of identity for honey, and noting that “your analysis of how your proposed standard of identity for honey would promote honesty and fair dealing in the interest of consumers is relevant to our consideration of your petition, since that is the statutory standard set forth in section 401 of the Act.”).

<sup>111</sup> *Fed. Sec. Adm’r v. Quaker Oats Co.*, 318 U.S. 218, 223 (1943) (internal quotations omitted).

The honesty and fair dealing standard requires consideration of consumers' interests.<sup>112</sup> Consumers increasingly desire meat and other animal products that are produced through humane practices protecting animal welfare, public health, and the environment.<sup>113</sup> U.S. consumers have also increasingly voiced increased concerns regarding chemicals, pharmaceuticals, and pesticides in their meat.<sup>114</sup> Petitioners' hundreds of thousands of members nationwide represent these interests. Allowing the use of drugs such as ractopamine, with unknown risks and effects, is wholly inconsistent with FDA's mandate under the FFDCFA to protect consumer health and safety. The agency's failure to offer the most stringent safeguards to consumers in light of international bans and strict limitations on use is confusing and misleading.

FDA action on ractopamine is the first line of defense to protect animal health, human health, and the environment from potentially harmful products. FDA has an obligation to protect consumers and offer security with respect to standards for food and drugs.<sup>115</sup>

#### **IV. FDA ACTION CANNOT BE ARBITRARY AND CAPRICIOUS**

In light of (1) the dearth of scientific research on ractopamine's effects on humans and animal welfare, and (2) the overwhelming number of countries that ban or restrict its use, FDA's refusal or failure to review current standards,

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<sup>112</sup> 21 U.S.C. § 1341.

<sup>113</sup> See *Meat on Drugs*, *supra* note 81; *U.S. Public's Awareness and Perceptions of Antibiotic Use in Food Animal Production*, Applegate, *supra* note 81; see also David S. Conner, Victoria Campbell-Arvai, & Michael W. Hamm, *supra* note 81; Demeter Commc'ns, *supra* note 73; Rauch & Sharp, *supra* note 74.

<sup>114</sup> See *Meat on Drugs*, *supra* note 81; *U.S. Public's Awareness and Perceptions of Antibiotic Use in Food Animal Production*, Applegate, *supra* note 81; see also David S. Conner, Victoria Campbell-Arvai, & Michael W. Hamm, *supra* note 81; Demeter Commc'ns, *supra* note 73; Rauch & Sharp, *supra* note 74.

<sup>115</sup> 21 U.S.C. § 393(b); see also *Lane Labs-USA, Inc.*, 427 F.3d at 226-27; *United States v. Two Bags, Poppy Seeds*, 147 F.2d at 128.

undertake studies, or to adjust ractopamine levels in the U.S. to protect health and welfare based standards is arbitrary and capricious action under the APA.<sup>116</sup>

FDA's mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and to protect the public health by ensuring that "foods are safe, wholesome, sanitary and properly labeled."<sup>117</sup> The statute requires a precautionary approach to the safety of food, drugs, devices, and cosmetics (e.g., substances which *may* render a food injurious to health shall be deemed to be adulterated under 21 U.S.C. § 342).

Under the FDA's regulation, 21 C.F.R. § 130.6(a), FDA has a duty to review all Codex standards.<sup>118</sup> FDA's failure to undertake Codex review, to commission comprehensive scientific studies, and to consider setting health- and welfare-based standards are decisions subject to judicial review under the APA. Under the APA, the court "shall . . . set aside" an agency's decision if it is arbitrary, capricious, or "otherwise not in accordance with law," or if it was adopted "without observance of procedure required by law."<sup>119</sup> The court must conclude that "the agency supplied a "rational connection between the facts found and the choice made."<sup>120</sup> Agency decisions that rely on factors that entirely fail to consider important aspects to

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<sup>116</sup> 5 U.S.C. § 706(2).

<sup>117</sup> 21 U.S.C. § 393(b)(1), (2)(A).

<sup>118</sup> *Id.* ("All food standards adopted by the Codex Alimentarius Commission *will be reviewed . . .*") (emphasis added).

<sup>119</sup> 5 U.S.C. § 706(2)(A), (D).

<sup>120</sup> *Bluewater Network v. Salazar*, 721 F. Supp. 2d 7, 22 (D.D.C. 2010) (citing *Motor Vehicle Mfrs. Ass'n of U.S.*, 463 U.S. at 43); *see also Volkswagenwerk Aktiengesellschaft v. FMC*, 390 U.S. 261, 272 (1968) (stating that the court must not "rubber-stamp...administrative decisions...inconsistent with a statutory mandate or frustrate the congressional policy underlying a statute." (quoting *NLRB v. Brown*, 380 U.S. 278, 291 (1965)); *see also Office of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1422-24 (D.C. Cir. 1983).

problems, or that offer explanations for decisions that run counter to the evidence before the agency, are arbitrary and capricious.<sup>121</sup>

That Codex standards are now more protective than FDA tolerances, and that the majority of the world follows standards even more protective of human and animal health than Codex, underscores the need for an immediate review, study, and adjustment of FDA tolerances pursuant to 21 C.F.R. § 130.3. “[A]ll regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious. . . .”<sup>122</sup> The international prevalence of strict ractopamine standards, and bans on the drug altogether, strongly suggest that ractopamine is poisonous or deleterious at Codex standards and at U.S. levels.<sup>123</sup> In light of the available evidence and FDA’s statutory obligations, its failure or refusal to act is arbitrary and capricious.<sup>124</sup>

## **V. SCIENTIFIC STUDY OF RACTOPAMINE IS INADEQUATE; GREATER EVALUATION IS NECESSARY**

There is a lack of information about the effects of ractopamine, and the information available is faulty, weak, and incomplete. Thus, due to the lack of scientific data and studies analyzing human health, animal welfare, and environmental effects, the safety of ractopamine is called into question because the current FDA tolerance levels cannot be scientifically supported.<sup>125</sup> Due to the

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<sup>121</sup> *Bluewater Network*, 721 F. Supp. 2d at 22 (internal quotations omitted).

<sup>122</sup> 21 C.F.R. § 130.3(c).

<sup>123</sup> *Compare*, Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt, 74 Fed. Reg. 2,443, 2,455 (proposed Jan. 15, 2009) (codified at 21 C.F.R. Part 131.200) (“After considering all relevant issues, including the safety concerns related to vitamin A addition, FDA tentatively concludes that the best approach is to revoke the existing lowfat and nonfat yogurt standards. . . .”).

<sup>124</sup> 5 U.S.C. § 706(2).

<sup>125</sup> 21 U.S.C. § 360b(a)(6).

complete lack of data on ractopamine’s effects on animal welfare, human health, and the environment, the “substantial evidence” standard required to continue a determination that ractopamine is safe and effective under the FFDCa is not satisfied.<sup>126</sup> Ractopamine’s initial approval by FDA as a NAD and its subsequent use approvals were supported by insufficient animal and human toxicology and exposure testing and environmental analysis. Under the FFDCa, the Secretary must refuse NAD applications if there are no “adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use” or that the “results of such tests show that such drug is unsafe for use.”<sup>127</sup> FDA approval of NADs typically does not evaluate “the absolute safety of the drug,” but rather “whether to allow the sale of the drug, usually under specific restrictions.”<sup>128</sup> Congress has thus authorized the agency to establish tolerance levels in residues, and also provides the agency with the power of “withdrawing approval ... [if] experience or scientific data show that such drug is unsafe. . . .”<sup>129</sup>

Ractopamine studies rarely, if ever, look for adverse effects of the drug on animal behavior, human health, or animal welfare. The studies on which the Codex standards are based suffer from the same flaws.<sup>130</sup> Existing data, as well as the lack of existing data, undercuts any support for FDA’s current ractopamine rules.

Existing studies do not adequately evaluate the risks of ractopamine to consumers.

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<sup>126</sup> 21 U.S.C. § 360b(d)(3); *see also Am. Cyanamid Co. v. Young*, 770 F.2d 1213, 1220 (D.C. Cir. 1985) (finding evidence supporting request to market dog flea product on an over-the-counter basis not up to scratch of the “substantial evidence” standard).

<sup>127</sup> 21 U.S.C. § 360b(d)(1)(A)-(B).

<sup>128</sup> *Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 754 (D.C. Cir. 1980) (quoting *Hess & Clark v. FDA*, 495 F.2d 975, 993-94 (D.C. Cir. 1974).

<sup>129</sup> 21 U.S.C. § 360b(e)(1)(A).

<sup>130</sup> *See* discussion *supra* Statement of Factual Grounds, secs. II and III.

Most studies evaluate what the proper dosage is in livestock in order to obtain the desired feed efficiency, weight gain, and meat leanness.<sup>131</sup> They do not specifically evaluate the effects of various dosages on animal welfare. Studies indicate that ractopamine effects differ by species.<sup>132</sup> This is an important factor in evaluating the effects of ractopamine because some species may be more sensitive to the drug than others.<sup>133</sup> Regardless of our current rules, it is certain that ractopamine is present in our food supply: a recent Consumers Union study tested some 240 pork products for ractopamine, and found residual amounts of the drug in about one-fifth of the samples tested.<sup>134</sup> And yet the warning signs are there.

First, the Codex human study was sponsored by ractopamine manufacturer Elanco, and it extraordinarily limited in scope to six healthy adult males (one of whom withdrew from the study).<sup>135</sup> Such study is an insufficient basis to simply overlook potential human health problems from ractopamine. A small size sample from a drug-company sponsored study should not be the only ground for allowing the use of a NAD by the major beef, swine, and turkey producers of the world.

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<sup>131</sup> See, e.g., J. Van Donkersgoed et al., *supra* note 66 at 116 (comparing economic value of Zilmax to Optaflexx); D.J. Smith & G.D. Paulson, *Growth Characteristics of Rats Receiving Ractopamine Hydrochloride and the Metabolic Disposition of Ractopamine Hydrochloride After Oral or Intraperitoneal Administration*, 72 J. of Animal Sci. 404 (1994) (measuring effects of ractopamine on growth rates).

<sup>132</sup> See, e.g., Harry J. Mersmann, *Overview of Effects of  $\beta$ -Andrenergic Receptor Agonists on Animal Growth Including Mechanisms of Action*, 76 J. of Animal Sci. 160, 160, 162 (1998) (noting the varying effects in different species, species selection factors, and the effectiveness of beta-agonists in different species).

<sup>133</sup> See, e.g., *Safety Evaluation of Ractopamine*, *supra* note 51, at 1 (“Comparing dog and monkey data it appeared that the dog could be considered as more sensitive to ractopamine.”).

<sup>134</sup> Press Release, Consumers Union, Consumer Reports Investigation of Pork Products Finds Potentially Harmful Bacteria Most of Which Show Resistance to Important Antibiotics (Nov. 27, 2012), <http://pressroom.consumerreports.org/pressroom/2012/11/my-entry-4.html>

<sup>135</sup> Helena Bottemiller, *Behind the Global Fight Over Livestock Drug*, Food & Environment Reporting Network, 2012, <http://thefern.org/behind-the-global-fight-over-livestock-drug/> (last visited Dec. 13, 2012); Helena Bottemiller, *Dispute Over Drug in Feed Limiting U.S. Meat Exports*, *supra* note 15.

Second, existing scientific research on ractopamine does meaningfully address animal welfare, human health, environmental concerns. Animal welfare has not been comprehensively considered in any study. Existing studies on animals demonstrate health problems, or changes in behavior and psychology,<sup>136</sup> but do not consider animal welfare in light of the health problems ractopamine causes. Third, this agency's own NEPA analysis concluded that there existed a "high amount of uncertainty" associated with chronic exposure to ractopamine. A drug with a "high amount of uncertainty" cannot also reasonably be safe and effective. Such a conclusion would be incongruous and contrary to the purposes of the FFDCA. Finally, existing studies do not demonstrate the safety or effectiveness of ractopamine.<sup>137</sup>

Each of the referenced weaknesses in existing studies has an important role in why current FDA and Codex standards are inadequate to protect animal welfare, human health, and the environment.<sup>138</sup> First, economic evaluations of the use of ractopamine in food-producing animals have nothing to do with animal or human health, which are the primary interests FDA must protect under the FFDCA.<sup>139</sup> Second, studies suggest ractopamine has different effects in different species.<sup>140</sup> For example, dogs have been found to be more sensitive to ractopamine than

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<sup>136</sup> See, e.g., J.N. Marchant-Forde et al, *The effects of ractopamine on the behavior and physiology of finishing pigs*, 81 J. Anim. Sci. 416 (2003).

<sup>137</sup> For example, "[t]here are limited and inconsistent data on the effect of Optaflexx in feedlot heifers on improving performance and carcass characteristics." J. Van Donkersgoed et al., *supra* note 66.

<sup>138</sup> See *supra* Statement of Factual Grounds, Secs. II & III; Statement of Legal Grounds, Sec. V.

<sup>139</sup> The FFDCA "was not designed primarily for the protection of merchants and traders; but was intended to protect the consuming public." *Two Bags, Poppy Seeds*, 147 F.2d at 128.

<sup>140</sup> See, e.g., Harry J. Mersmann, *supra* note 132.

monkeys.<sup>141</sup> More studies should be done to probe the differences that exist, and why. Third, any study based on small samples and purely commercial factors rather than the health of animals, humans, animal welfare, or the environment; should be of no import to FDA's tolerance levels for ractopamine because the FFDCAs purpose is to protect consumers. Finally, the U.S. does not even currently employ comprehensive ractopamine testing, which is years behind other nations.<sup>142</sup>

FDA must "shape its administrative actions when it has reason to doubt the safety of a new animal drug."<sup>143</sup> The lack of adequate science on the safety or effectiveness of ractopamine raises more than a mere "shadow" of a doubt. Other nations have determined that the dearth of information actually requires them to ban the use of the drug. Thus, to protect animal welfare, human health, and the environment, FDA should undertake comprehensive scientific studies. To truly understand the drug's effects on animals and humans and analyze tolerance levels (and not just effectiveness levels), FDA must immediately undertake comprehensive studies.

## **VI. REASONS SUPPORTING DEVIATION FROM CODEX STANDARDS**

As required by 21 C.F.R. § 130.6, Petitioners request FDA to deviate from Codex standards by setting a more stringent standard for the U.S. based on health and animal welfare considerations. With respect to the deviations, Petitioners incorporate the reasons stated in this Petition and state as follows:

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<sup>141</sup> Safety Evaluation of Ractopamine, *supra* 51, at 1.

<sup>142</sup> See, e.g., Helena Bottemiller, *Dispute Over Drug in Feed Limiting U.S. Meat Exports*, *supra* note 15.

<sup>143</sup> *Cyanamid Co.*, 770 F.2d at 1216 (quoting *Rhodia, Inc., v. FDA*, 608 F.2d 1376, 1380-81 (D.C. Cir. 1979)).

1. The U.S. is one of the largest producers of pork, cattle, and turkeys in the world. Approximately 160 nations, or 81% of the world, do not approve the use of ractopamine or the import of livestock products containing the drug;
2. Codex standards for ractopamine do not adequately protect public health, animal welfare, or the environment;
3. Codex standards for ractopamine are scientifically compromised, based on unreliable and weak data, and apply study results to reach conclusions regarding human health that were not part of the study's intent; and
4. Additional research regarding the safety of ractopamine with regard to animals, humans, animal welfare, and the environment must be conducted.

### **CONCLUSION**

Petitioners request that FDA immediately undertake the following actions:

- (1) Review the Codex standards for ractopamine as established in July 2012;
- (2) Publish this Petition in the Federal Register as a proposal;
- (3) Provide opportunity for public comment on the Petition;
- (4) Perform comprehensive scientific studies needed to characterize the health, welfare, and behavioral risks posed by the use of ractopamine in food-producing animals, including studies of animal toxicity of the drug with its metabolites (including, but not limited to, their genotoxicity, carcinogenicity, and any cardiovascular, reproductive, endocrine, musculoskeletal, or behavioral effects they may elicit), animal behavioral effects of the drug (including but not limited to social behaviors), and animal exposure to residues of the drug and its metabolites in edible tissues;
- (5) Perform comprehensive scientific studies needed to characterize human food safety risks posed by the use of ractopamine in food-producing animals, including studies of human toxicity of the drug with its metabolites (including, but not limited to, their genotoxicity, carcinogenicity, and any cardiovascular, reproductive, endocrine, musculoskeletal, or behavioral effects they may elicit) and human

exposure to residues of the drug and its metabolites in the edible tissues of food-producing animals;

- (6) Perform comprehensive scientific studies to characterize the environmental risks posed by the use of ractopamine in food-producing animals; and
- (7) Pending Codex review and comprehensive scientific studies, significantly strengthen U.S. standards by:
  - a. Deviating from Codex standards for ractopamine and setting more health- and welfare-based standards;  
  
or, in the alternative if FDA determines it will not or cannot perform this act:
  - b. Meeting Codex standards for ractopamine.

#### **STATEMENT OF CONFERENCE**

FDA regulations encourage but do not require interested persons submitting petitions to FDA under 21 C.F.R. § 130.6 to confer with different interest groups. In formulating this Petition, the Petitioners state that they have conferred with different interest groups and considered different interest groups' approaches to this issue.

#### **ENVIRONMENTAL IMPACT STATEMENT**

The specific actions requested by Petitioners will not cause the release of any substance into the environment. They are categorically excluded from the requirement of environmental documentation under 21 C.F.R. § 25.33(g).

#### **ECONOMIC IMPACT STATEMENT**

The requested information is only required when requested by the Commissioner following the review of the petition, and therefore an economic impact statement is not provided at this time.

**CERTIFICATION**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners that are unfavorable to the Petition.

Respectfully Submitted,

\_\_\_\_\_/s/\_\_\_\_\_  
Daniel Lutz  
Litigation Fellow  
Carter Dillard  
Litigation Director  
Animal Legal Defense Fund

\_\_\_\_\_/s/\_\_\_\_\_  
Elisabeth Holmes  
Staff Attorney  
Paige Tomaselli  
Senior Staff Attorney  
Center for Food Safety

**ENDORISING ORGANIZATIONS**

The following organizations have endorsed this petition to FDA:

Community Association for Restoration of the Environment  
Consumers Union  
Environmentally Concerned Citizens of South Central Michigan  
Food & Water Watch  
Midwest Environmental Advocates  
Public Employees for Environmental Responsibility