**PETITION BEFORE THE UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE**

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| **ANIMAL LEGAL DEFENSE FUND**<br>170 E. Cotati Ave.<br>Cotati, CA 94931<br>707-779-2055 | ) |
| *Petitioner,* | ) |
| ***Filed with:*** | ) |
| **TOM VILSACK**<br>in his official capacity as Secretary,<br>United States Department of Agriculture<br>1400 Independence Avenue SW<br>Washington, DC 20250 | ) |
| and | ) |
| **ALFRED ALMANZA**<br>in his official capacity as Administrator<br>Food Safety and Inspection Service<br>United States Department of Agriculture<br>1400 Independence Avenue SW<br>Washington, DC 20250 | ) |

**CITIZEN'S PETITION SEEKING MANDATORY MEAT AND POULTRY LABELING TO PREVENT THE SALE OF MISBRANDED PRODUCTS**

## I. INTRODUCTION

Pursuant to applicable Food Safety and Inspection Service ("FSIS") regulations, 9 C.F.R. § 392, and the Administrative Procedure Act, 9 U.S.C. § 551 *et seq*. ("APA"), the Animal Legal Defense Fund ("ALDF") submits this petition for rulemaking to request that the United States Department of Agriculture's ("USDA") FSIS take regulatory action to require mandatory

labeling of meat and poultry products by meat and poultry producers to disclose routine antibiotic use in meat and poultry production, and to clarify the standard for "antibiotic free"[1] type labeling claims. The abuse of antibiotics in conventional animal agriculture has unique and far-reaching human health consequences, yet companies do not have to disclose antibiotic use to consumers. Because product packaging is the primary source of information for consumers, a company's failure to reveal the uniquely material facts about antibiotic use creates consumer confusion and prevents informed purchasing choices that could otherwise diminish individual and public demand for harmful products and thereby prevent a clear and potentially devastating threat to public health.

Consumers are increasingly familiar with the threat posed by abuse of antibiotics in agriculture, but they are prevented from linking that knowledge to particular products because current labels, and labeling regulations, conceal information about antibiotic use. Consumers are thus prevented from making informed purchasing decisions to avoid particular products and thereby prevented from diminishing the clear and unique threat antibiotic use poses to their and the public's health. The obvious solution is to require the simple disclosure of antibiotic use, much the way other federal labeling regulations require the disclosure of product attributes that pose unique threats to the health and safety of individual consumers and the public in general.[2]

The fact that producers who do not use antibiotics may voluntarily label their products as such does not assuage this problem; it merely compounds consumer misinformation, because the wording of such claims is variable, and consumers may not understand the meaning of such claims. Indeed, with the myriad of disparate labels currently used in the marketplace, survey

[1] Although this term may not be used on product packaging, Petitioners use it herein to refer to all claims indicating that animals are raised without antibiotics.

[2] See, e.g., 21 CFR 101.9(c), (c)(2)(ii)-(iv), which requires food companies to list trans fat content on their product labels because of the link between trans fat and coronary heart disease.

evidence illustrating that these labels are inherently confusing, and federal precedent that confirms some of these labels constitute false advertising under the Lanham Act, FSIS is statutorily mandated to require meat producers to provide more meaningful, consistent information to consumers to prevent further threats to public health. The current system fails to reveal to consumers certain material facts that would, and should, substantially influence their purchasing decisions and is therefore contrary to FSIS's enabling statutes. For the reasons set forth herein, ALDF requests that FSIS take immediate action and initiate rulemaking to require accurate disclosure of antibiotic use by meat and poultry producers.

## II. INTERESTS OF PETITIONER

Petitioner ALDF is a national nonprofit organization that works to protect the lives and advance the interests of animals through the legal system. ALDF has spent over three decades focusing on issues involving animals and the law, with a focus on assisting agencies, courts, and legislatures in carrying out the public policy against animal cruelty and advancing the protection of the interests of animals through the legal system. Based in Cotati, California, ALDF represents over 110,000 members, is supported by hundreds of dedicated *pro bono* attorneys, and supports 171 student ALDF chapters in law schools throughout the United States. ALDF has been involved in the protection of animals used and sold in commercial enterprises, frequently with a focus on cruelty and the intensive confinement of animals used for food.

Farming has changed dramatically over the past few decades, with many farms now operating large-scale industrial agricultural facilities where animals are raised in high-density confinement. Meat producers raise animals in high-density confinement to produce the highest output possible, but to be able to do so they rely on the use of antibiotics, administered at low levels in animal feed, to reduce the chance for infection and to eliminate the need for animals to

expend energy fighting off bacteria. While meat producers benefit from increased, faster growth and higher yields of meat with less animal feed, animals suffer tremendously as a result.

Indeed, meat producers are essentially relieved from providing animals with clean living conditions and room to live comfortably, instead relying on antibiotics to keep animals from getting sick as a result of these overcrowded and poor living conditions. Animals live a lifetime of confinement, often suffering from discomfort and injuries caused by inappropriate flooring and housing; restriction and outright prevention of normal exercise, foraging, exploratory behavior, and natural maternal behavior; poor air quality; debeaking in the poultry and egg industry to avoid pecking in overcrowded quarters; and social stress and injuries due to overcrowding – among many other ailments. ALDF has an interest in preventing such tremendous animal suffering, to which subtherapeutic antibiotic usage contributes significantly. Indeed, the use of antibiotics in the farming industry helps enable meat producers to maintain appalling living conditions for farm animals without any effect on their bottom line. Without the use of subtherapeutic antibiotics, the factory farming model currently in existence would need to be modified significantly to alleviate the intense confinement made possible through such antibiotic usage. ALDF has an interest in promoting animal welfare by encouraging the purchase of products that are not produced through low-welfare, and arguably illegal, standards, as described herein.

Not only does antibiotic use contribute to animal suffering, but it also contributes to a public health crisis – the proliferation of antibiotic resistance that could turn once-simple bacterial infections into fatal conditions. Consumers have the right not to contribute to such farming practices by choosing not to purchase products that come from animals raised with antibiotics, but they are paralyzed by the current labeling scheme, which fails to require meat

producers to provide meaningful information about antibiotic usage. If consumers are provided with this necessary information, they will purchase fewer meat products that come from animals raised with antibiotics,[3] lessening demand for such meat products. In turn, meat producers will be forced to change their practices to decrease antibiotic usage and improve farming conditions. As a result, animal welfare will be improved.

Furthermore, some ALDF members eat meat and poultry products. These members rely on product packaging to ensure the safety and wholesomeness of their food, and to avoid patronizing and thereby promoting certain industry practices that threaten public health generally. FSIS is responsible for ensuring that meat and poultry products are wholesome, not adulterated, and properly marked and labeled, and ALDF members depend on USDA assurances when selecting meat and poultry products for that reason. ALDF members are harmed by the current FSIS labeling policy, which fails to provide uniform, meaningful disclosure of antibiotic use on the farm. Many ALDF members, as well as members of the general public, desire "antibiotic free" meat and poultry for a number of reasons, including personal and public health concerns and the desire to refrain from supporting meat and poultry producers who use antibiotics in their animal feed. They also desire products which minimize their exposure to potentially fatal antibiotic-resistant bacteria – which is found in greater quantities on meat that comes from animals raised with antibiotics. The only source of information about antibiotic usage in meat products is the product label on meat and poultry products, and the current regulatory scheme, which permits, but does not require, labeling of antibiotic use, prevents ALDF members from making informed purchasing decisions.

[3] See Section IV.a.iv below.

## III. SPECIFIC REQUEST FOR AGENCY ACTION

Pursuant to the APA, 5 U.S.C. § 553(e), the Petitioner hereby requests that FSIS initiate rulemaking to amend the regulations governing the labeling of meat and poultry products in order to require mandatory disclosure of antibiotic use by meat and poultry producers. The factual and legal background set out below supports the adoption of the following regulations:

Amendment to poultry product labeling regulations, 9 C.F.R. § 381.129:

> (g) Mandatory disclosure of antibiotic use. A statement disclosing antibiotic use in poultry shall appear on the label of all poultry products subject to the Act. Labels shall include the following language:
>
> > (1) Where products are from poultry who receive antibiotics for any reason, including growth promotion and disease prevention, the label shall contain the language: “From Poultry Raised With Antibiotics" or "From Poultry Fed Antibiotics." This requirement shall not apply to poultry who receive antibiotics for the sole purpose of treating disease or injury.
> >
> > (2) Where products are from poultry who never receive antibiotics, the label shall contain the language: “From Poultry Raised Without Antibiotics.”
> >
> > (3) Where products are from poultry who receive antibiotics for the sole purpose of treating disease or injury, the label shall contain the language “From Poultry Given Antibiotics for Therapeutic Antibiotic Use Only.”
> >
> > (4) The appropriate designation shall be printed so as to appear prominently and conspicuously on the principal display panel of the package in a type size no smaller than $1/8^{th}$ of an inch and placed with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary use.

Amendment to meat product labeling regulations, 9 C.F.R. § 317.8:

> (41) Mandatory disclosure of antibiotic use. A statement disclosing antibiotic use in animals shall appear on the label of all meat products subject to the Act. Labels shall include:
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> > (i) Where products are from animals who receive antibiotics for any reason, including growth promotion and disease prevention, the label shall contain the language: “From Animals Raised With Antibiotics" or "From Animals Fed Antibiotics." This requirement shall not apply to animals who receive antibiotics for the sole purpose of treating disease or injury.

(ii) Where products are from animals who never receive antibiotics, the label shall contain the language: "From Animals Raised Without Antibiotics."

(iii) Where products are from animals who receive antibiotics for the sole purpose of treating disease or injury, the label shall contain the language "From Animals Given Antibiotics for Therapeutic Antibiotic Use Only."

(iv) The appropriate designation shall be printed so as to appear prominently and conspicuously on the principal display panel of the package in a type size no smaller than $1/8^{th}$ of an inch and placed with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary use.

## IV. STATEMENT OF GROUNDS SUPPORTING REQUESTED ACTION

### a. Factual Background

#### i. Antibiotics are rampantly abused in industrial animal agriculture.

In step with the post-World War II rise of industrial animal agriculture and concentrated animal feeding operations ("CAFO") across the United States, in the 1950s, the U.S. Food and Drug Administration ("FDA") "approved the use of antibiotics to stimulate growth and improve feed efficiency in food-producing animals, such as cattle, swine, and chickens."[4] Indeed, the mass administration of antibiotics at "subtherapeutic"[5] levels has become a necessary standard practice in CAFOs in order to stave off increased rates of disease that invariably accompany the high-density, and often unsanitary, close-confinement inherent in the CAFO model. Stress caused by confinement, the inability to express natural behaviors and unnatural animal peer groups presents challenges to the immune systems of factory farmed animals, and agribusiness has turned to subtherapeutic doses of antibiotics as a quick fix, rather than addressing the unsanitary and unnatural conditions themselves. Additionally, the drugs appear to promote faster animal growth on less feed, which saves producers money and maintains efficient mass

[4] Ex. A, *National Resources Defense Council (NRDC) v. U.S. Food & Drug Admin.* (FDA), 884 F. Supp. 2d 127 (2012).

[5] In contrast to antibiotic administration at approved doses for disease treatment, the administration of "subtherapeutic" antibiotics refers to the use of antibiotics in food-producing animals for growth promotion and feed efficiency at doses too low to treat disease. *Id.* at n. 3.

production because the animals reach slaughter weight faster.[6] In the end, misusing antibiotics is a win-win situation for agribusiness, but a lose-lose situation for the animals and, ultimately, consumers and public health in general.

By 2009, the lion's share (80%) of antibiotics sold in the U.S. went to livestock, roughly 90% of which was administered at subtherapeutic levels. Specifically, the FDA reports that in 2009 just over 13 million kilograms of antibiotics were sold or distributed for use in food-producing animals in the U.S., compared to the estimated 3.3 million kilograms of antibiotics sold in the U.S. for human use that year.[7] Of the antibiotics sold for use in livestock, 11.8 million kilograms – or 90% – were sold for mass administration via animal feed or water, rather than for administration via injection.[8]

**ii. Overuse of antibiotics in animal agriculture has created antibiotic-resistant "superbugs."**

The profits that producers have reaped by abusing antibiotics as prophylaxes and growth-promoters have, however, come at a troubling cost. The improper use and overuse of antibiotics – specifically penicillin and tetracyclines – have led to a phenomenon known as antibiotic resistance. That is, "the misuse of antibiotics creates selective evolutionary pressure that enables antibiotic resistant bacteria to increase in numbers more rapidly than antibiotic susceptible

[6] Ex. B, excerpt from: Mark S. Smolinksi, et al., *Microbial Threats to Health: Emergence, Detection, and Response*, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES (2003), at 207-208.

[7] Ex. C, *2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, FDA (2010), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFee ActADUFA/ UCM231851.pdf, at 3; Ex. D, Letter from Karen Meister, Supervisory Congressional Affairs Specialist, to Louise M. Slaughter, United States Representative (D-NY) (Apr. 19, 2011), at 4.

[8] Letter from Karen Meister, Supervisory Congressional Affairs Specialist, to Louise M. Slaughter, United States Representative (D-NY) (Apr. 19, 2011), at 1.

bacteria, increasing the opportunity for individuals to become infected by resistant bacteria."[9] Once resistant bacteria are present, single resistance genes are capable of jumping among different bacteria in the same family, creating new superbugs on the spot.[10]

Empirical studies extensively document that food animals have become "reservoirs"[11] of antibiotic-resistant pathogens – including *Salmonella*, *Campylobacter*, and *E. coli*.[12] Data collected by the National Antimicrobial Resistance Monitoring System ("NARMS") in 2009 indicate that *Salmonella* was present on 21% of retail chicken breast samples and 14.4% of retail ground turkey samples, and nearly half (48.4%) of the *Salmonella* on chicken breasts and more than a quarter (26.3%) of the *Salmonella* from ground turkey was resistant to three or more classes of antibiotics. Tertracycline resistance was common among *Salmonella* isolates from chicken and turkey products (59.9% and 65.3%, respectively), while resistance to ampicillin (an antibiotic in the penicillin class) was only slightly less common at 45.8% of chicken *Salmonella* and 57.9% of turkey *Salmonella*. The NARMS *2009 Retail Meat Report* also shows that *Campylobacter*, including *Campylobacter jejuni* and *Campylobacter coli* species, was present on 44.1% of retail chicken breasts tested, and nearly half (46.2%) of the *C. jejuni* isolates and more than one third (38.0%) of the *C. coli* isolates were resistant to tetracycline. Moreover, the

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[9] Ex. E, *The Overuse of Antibiotics in Food Animals Threatens Public Health*, CONSUMER REPORTS (Nov. 9, 2012), http://consumersunion.org/wp-content/uploads/2013/02/Overuse_of_Antibiotics_On_Farms.pdf

[10] Ex. F, Peter Eisler, *Drugs Can't Stop This Killer*, USA TODAY, Nov. 29, 2012, at 1A.

[11] Ex. G, *Ch. 4: Reducing the use of antibiotics in animal husbandry*, WORLD HEALTH ORGANIZATION, THE EVOLVING THREAT OF ANTIMICROBIAL RESISTANCE: OPTIONS FOR ACTION (2012), http://whqlibdoc.who.int/publications/2012/9789241503181_eng.pdf.

[12] Ex. H, Letter from Thomas R. Frieden, M.D., M.P.H., Director, CDC and Administrator, Agency for Toxic Substances and Disease Registry to the Honorable Frank Pallone, Jr., Chairman, Subcommittee on Health (July 13, 2010), cover letter at 1; Ex. I, Antibiotic Resistances: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals, GAO-04-490 (April 2004), at 11, 17-23; Ex. J, *2009 Retail Meat Report, National Antimicrobial Resistance Monitoring System*, FDA(2009), http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM257587.pdf.

NARMS *2009 Retail Meat Report* indicates that *E. coli* was highly prevalent on all meat types tested: chicken breasts (87.5%); ground turkey (85.0%); ground beef (68.8%); and pork chops (40.8%). Multidrug resistance was most prevalent among *E. coli* isolates from chicken breasts (37.5%) and ground turkey (66.3%), with approximately 56.2% of *E. coli* isolates from ground turkey resistant to ampicillin and 82.0% resistant to tetracycline.[13]

In addition to the NARMS *2009 Retail Meat Report*, other scientific literature is rife with data corroborating that the pervasive administration of subtherapeutic antibiotics in industrial animal agriculture is directly responsible for the unprecedented rise of antibiotic resistance.[14] For example, the World Health Organization ("WHO") reports that "[b]acteria and resistance to critically important antimicrobial agents associated with food animals include: *Escherichia coli* and *Salmonella* ssp resistant to 3rd and 4th generation cephalosporins and to fluoroquinolones; *Campylobacter* ssp resistant to macrolides and fluoroquinolones; *Staphylococcus aureus* resistant to all beta-lactam-type drugs (i.e., MRSA [Methicillin-Resistant *Staphylococcus aureus*]); [and] enterococci resistant to vancomycin (VRE) and *C. difficile*."[15] A 2006 study published in *Water Science and Technology* investigated groundwater contamination from antibiotic-resistant *E. coli* originating from industrial swine farms in eastern North Carolina, and concluded that 68% of the *E. coli* from swine farm sites was resistant to at least one antibiotic.[16] Moreover, a 2007 study published in the *Journal of Food Protection* concluded that the

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[13] *2009 Retail Meat Report, National Antimicrobial Resistance Monitoring System*, FDA(2009).

[14] See Ex. K, *Antibiotic Resistance and Food Animal Production: a Bibliography of Scientific Studies (1969-2012)*, THE PEW CHARITABLE TRUSTS http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Issue_Briefs/HHIFBibliographyFinal%20with%20TOC%20_071712.pdf.

[15] *Ch. 4: Reducing the use of antibiotics in animal husbandry*, WORLD HEALTH ORGANIZATION, THE EVOLVING THREAT OF ANTIMICROBIAL RESISTANCE: OPTIONS FOR ACTION (2012), note 9 at 52.

[16] Ex. L, M.E. Anderson & M.D. Sobsey, *Detection and occurrence of antimicrobially resistant E. coli in groundwater on or near swine farms in eastern North Carolina*, 54:3 WATER SCIENCE AND TECHNOLOGY, 211-18 (2006).

development of macrolide-resistant *Campylobacter* in broiler chickens tracks the administration of subtherapeutic concentrations of tylosin in chicken feed.[17]

Recent investigations by Consumer Reports have independently confirmed such findings. A 2010 investigation on store-bought chickens revealed that *Campylobacter* was present in 62% of the chickens analyzed, *Salmonella* was present in 14%, and both bacteria were present in 9%. Even more troubling, Consumer Reports found that 68% of the *Salmonella* and 60% of the *Campylobacter* organisms analyzed showed resistance to one or more antibiotics.[18] A recent investigation on pork chop and ground pork samples found that *Yersinia Enterocolitica* and other bacteria existed on a significant percentage of the meat tested, some of which "proved to be resistant to antibiotics commonly used to treat people."[19] The most recent analysis published by the Environmental Working Group detected antibiotic-resistant bacteria in 81% of ground turkey, 69% of pork chops, 55% of ground beef, and 39% of chicken breasts, wings and thighs.[20] Even worse: the proportion of antibiotic-resistant germs found in meat samples is on the rise.[21]

A ban by the Danish government on the subtherapeutic use of antibiotics has further proven the correlation between subtherpeutic use and antibiotic resistance.[22] Indeed, the ban of

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[17] Ex. M, S.R. Ladely et al., *Development of macrolide-resistant Campylobacter in broilers administered subtherapeutic or therapeutic concentrations of tylosin*, 70:8 JOURNAL OF FOOD PROTECTION, (2007) 1945-1951.

[18] Ex. N, *How safe is that chicken?*, CONSUMER REPORTS (Jan. 2010), http://www.consumerreports.org/cro/magazine-archive/2010/january/food/chicken safety/overview/chicken-safety-ov.htm.

[19] Ex. O, *What's in that pork?*, CONSUMER REPORTS (Jan. 2013), http://www.consumerreports.org/cro/pork0113.htm.

[20] Ex. P, *Superbugs Invade American Supermarkets*, ENVIRONMENTAL WORKING GROUP (April 2013), http://www.ewg.org/meateatersguide/superbugs/.

[21] *Id.*

[22] Ex. Q, Per Hennksen, DVM, PhD, Ministry of Food, Agriculture & Fisheries, Danish Testimony on the July 14th Hearing about Antibiotic Resistance in the Livestock Industry Organized by the Subcommittee on Health (July 12, 2010).

subtherapeutic antibiotic use has resulted in the reduction in antimicrobial resistance as measured among several different bacterial species in food animals.[23] Furthermore, the food safety of Danish products of animal origin has significantly improved as it relates to *Salmonella* and *Campylobacter* bacteria.[24]

### iii. Subtherapeutic antibiotic use in animal agriculture is a major threat to human health.

The significant, and seemingly unstoppable, rise of antibiotic-resistant bacteria due to the administration of antibiotics in animal feed is creating a public health crisis. The WHO cautions, "[t]he fact that greater quantities [of antibiotics] are used in healthy animals than in unhealthy humans is cause for *serious concern*, particularly as some of the same antibiotics are involved, and food animals have been shown to carry resistant human pathogens."[25] Moreover, the Center for Disease Control ("CDC") concludes that there is a compelling body of evidence affirming the causal link between antibiotic use in food animals and adverse human health consequences, including a rise in resistant bacteria in humans resulting in increased and longer hospitalizations and heightened risks of debilitating and life-threatening infections.[26] Additionally, "[t]he FDA considers antibiotic resistance a mounting public health problem of global significance."[27]

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[23] *Id.*

[24] *Id.*

[25] *Ch. 4: Reducing the use of antibiotics in animal husbandry*, WORLD HEALTH ORGANIZATION, THE EVOLVING THREAT OF ANTIMICROBIAL RESISTANCE: OPTIONS FOR ACTION (2012), note 9 at 50 (emphasis added).

[26] See Letter from Thomas R. Frieden, M.D., M.P.H., Director, CDC and Administrator, Agency for Toxic Substances and Disease Registry to the Honorable Frank Pallone, Jr., Chairman, Subcommittee on Health (July 13, 2010), cover letter at 1; See also *NRDC v. FDA*, 884 F. Supp. 2d 127 (2012).at *132 ("[p]eople who contract antibiotic-resistant bacterial infections are more likely to have longer hospital stays, may be treated with less effective and more toxic drugs, and may be more likely to die as a result of the infection.").

[27] *Id.* The FDA is not alone in its concerns. Sally Davies, the chief medical officer of England, recently claimed that antibiotic resistance poses a "catastrophic threat" to public health. See Ex. R, *Antibiotic Resistance Poses "Catastrophic Threat" to Medicine, says Britain's Top Health Official*, HUFFINGTON

The spread of antibiotic-resistant bacteria from food animals to humans has been documented to occur via the consumption of inadequately cooked meat and poultry, the handling of raw meat and poultry, cross-contamination with other foods, the environment (e.g., airborne bacteria, contaminated soil and groundwater, or spray/runoff from CAFO effluent lagoons), and direct animal contact.[28] For example, *E. coli* with antibiotic-resistant genes has been found in drinking water near hog facilities in three states.[29] Studies have also demonstrated that resistant bacteria originating from livestock has been spread to farmers, who then spread bacteria to their family, friends and the public at large.[30] Farmers themselves have confirmed that they have contracted life-threatening antibiotic-resistant infections from their own animals.[31] Because these antibiotic-resistant microbes are spread easily through the environment, even individuals who do not consume meat are at risk of infection.

Contamination and, ultimately, infection come at an alarming cost. Though the approximately 48 million cases of food borne illness that occur each year in the U.S. are not regularly publicized, some cases tied directly to antibiotic resistance cause enough destruction to warrant attention.[32] For instance, in 2011 ground turkey was linked to 136 illnesses and one death, all caused by a strain of *Salmonella* that was resistant to four different antibiotics:

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POST (March 10, 2013), http://www.huffingtonpost.com/2013/03/10/antibiotic-resistance-catastrophic-threat_n_2850651.html.

[28] *Ch. 4: Reducing the use of antibiotics in animal husbandry*, WORLD HEALTH ORGANIZATION, THE EVOLVING THREAT OF ANTIMICROBIAL RESISTANCE: OPTIONS FOR ACTION (2012), note 9 at 51.

[29] Ex. S, *Raising Resistance: Feeding Antibiotics to Healthy Food Animals Breeds Bacteria Dangerous to Human Health*, National Resources Defense Counsel, October 2011, *available at* http://www.nrdc.org/health/files/raisingresistance.pdf.

[30] *Id.*

[31] Ex. T, Steve Ellis & Russ Kremer, Op-Ed., *Regulate the use of antibiotics on farm animals*, Denver Post (May 9, 2013), http://www.denverpost.com/opinion/ci_23201599/regulate-use-antibiotics.

[32] *The Overuse of Antibiotics in Food Animals Threatens Public Health*, CONSUMER REPORTS (Nov. 9, 2012), http://consumersunion.org/wp-content/uploads/2013/02/Overuse_of_Antibiotics_On_Farms.pdf

ampicillin, streptomycin, tetracycline and gentamicin, resulting in the recall of an estimated 36 million pounds of ground turkey.[33] In another case in 2011, ground beef sold in Hannaford grocery stores was linked to 19 infections and seven hospitalizations, caused by a strain of *Salmonella* resistant to multiple antibiotics, including amoxicillin/clavulanic acid, ampicillin, ceftriaxone, cefoxitin, kanamycin, streptomycin, and sulfisoxazole.[34]

Resistant bacteria from animals have been linked to other illnesses in humans. For instance, an increasing number of studies indicate that a major proportion of resistant *E. coli* that cause extra-bowel infections in humans, such as urinary tract infections ("UTI"), likely have their origins in food animals that have been administered antibiotics at subtherapeutic levels.[35] A 2005 study published in *Clinical Infectious Disease* concluded that drug-resistant uropathogenic, human-associated *E. coli* strains may have food animal origins, and that drug-resistant UTIs in humans could be derived from food borne illnesses.[36] Four studies from 2008 and 2010 confirmed this finding, concluding that the correlation between *E. coli* found in food animals and drug-resistant UTIs found in humans reveals that multidrug-resistant *E. coli* outbreaks are the causative agent of the UTIs.[37] The authors pointed directly to consumption and handling of

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[33] *Id.*

[34] *Id.*

[35] Ch. 4: Reducing the use of antibiotics in animal husbandry, WORLD HEALTH ORGANIZATION, THE EVOLVING THREAT OF ANTIMICROBIAL RESISTANCE: OPTIONS FOR ACTION (2012), note 9 at 54; Ex. U, JR Johnson et al. *Antimicrobial drug-resistant Escherichia coli from humans and poultry products, Minnesota and Wisconsin, 2002-2004,* 13:6 EMERGING INFECTIOUS DISEASES, 838-46 (2007); Ex. V, Warren RE et al. *Imported chicken meat as a potential source of quinolone-resistant Escherichia coli producing extended-spectrum beta-lactamases in the UK*, 61:3 JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY 504-08 (2008).

[36] Ex. W, L. Unicomb et al., *Low-level fluoroquinolone resistance among Camplyobacter jejuni isolates in Australia*, 42 CLINICAL INFECTIOUS DISEASES, 1368-74 (2006).

[37] Ex. X, A.R. Manges et al., *Endemic and epidemic lineages of Escherichia coli that cause urinary tract infections*, 14:10 EMERGING INFECTIOUS DISEASES 1575-83 (2008); Ex. Y, S.P. Smith, A.R. Manges, and L.W. Riley, *Temporal changes in the prevalence of community-acquired antimicrobial-resistant urinary tract infection affected by* Escherichia coli *clonal group composition*, 46 CLINICAL INFECTIOUS

contaminated food products, particularly poultry and pork, as the most likely source of the development of drug-resistant UTIs.[38]

Resistant bacteria create a number of other problems, for which the medical community has no current solutions, and none in the pipeline. First, of course, is patient safety. Doctors try antibiotic after antibiotic to stop these infections as they tear through a patient's body, even turning to "drugs of last resort," with no success in many cases.[39] Doctors are seeing an increased rate of infection by resistant bacteria that was "once-obscure" in medical institutions across the country, and they are concerned about being able to curb the spread of these infections.[40] The ability of resistant bacteria to defeat even the most potent antibiotics has conjured fears of illness that "can't be stopped."[41] Equally concerning is the effect these bacteria have on the medical community's ability to do its job. For instance, hospital units specializing in chemotherapy and organ transplants are "crippled" by their inability to control these infections in patients with weak immune systems.[42]

What is worse is that there is no quick fix. Industry experts and federal officials have confirmed that manufacturers "have no new antibiotics in development that show promise" and there is little financial incentive to develop them since resistant bacteria adapts quickly to resist

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DISEASES, 689-95 (2008); Ex. Z, C. Vincent et al., *Food reservoir for* Escherichia coli *causing urinary tract infections*, 16:1 EMERGING INFECTIOUS DISEASES, 88-95 (2010); Ex. AA, L. Jakobsen et al., Escherichia coli *isolates from broiler chicken meat, broiler chickens, pork, and pigs share phylogroups and antimicrobial resistance with community-dwelling humans and patients with urinary tract infection*, 7:5 FOODBORNE PATHOGENS AND DISEASE, 537-47 (2010).

[38] *Id.*

[39] Peter Eisler, *Drugs Can't Stop This Killer*, USA TODAY, Nov. 29, 2012, at 1A.

[40] *Id.* at 1A, 6A.

[41] *Id.*

[42] *Id.* at 6A.

new drugs.[43] Eli Perencevich, a professor and infectious-disease doctor at the University of Iowa's Carver College of Medicine, warns that if these bacteria go unchecked, they can ultimately impact the kinds of surgeries and treatments that hospitals can offer.[44] He cautions, "[w]e're entering the post-antibiotic era; that's a very big problem."[45] Doctors fear most that genes may start to convey resistance to more common strains of bacteria, which could turn routine illnesses like urinary tract infections into "untreatable nightmares."[46] Last year, Dr. Margaret Chan, director general of the WHO, said that if important antibiotics become useless, "things as common as strep throat or a child's scratched knee could once again kill."[47] Gary Roselle, director of the Infectious Diseases Service for the Department of Veterans Affairs health system, acknowledges that the prognosis with respect to resistant bacteria is not good, and that there likely will be no new drugs to treat them, which means "the focus has to be on prevention."[48]

Based on this widely-accepted information, which has been backed up by extensive scientific data, "the FDA has concluded that the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes [in livestock] is not in the interest of protecting and promoting the public health."[49] Indeed, the overwhelming weight of scientific authority has concluded that the use of subtherapeutic antibiotics in animal feed presents potentially dangerous – and perhaps deadly –

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[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Superbugs Invade American Supermarkets,* ENVIRONMENTAL WORKING GROUP (April 2013), http://www.ewg.org/meateatersguide/superbugs/.

[48] Peter Eisler, *Drugs Can't Stop This Killer*, USA Today, Nov. 29, 2012, at 1A.

[49] *NRDC v. FDA*, 884 F. Supp. 2d 127 (2012), at *132 (internal citations omitted).

risks to consumers who handle and eat the meat of such animals and to the public at large.[50] This information is not novel or ground-breaking; in fact, the FDA has known about this for over four decades but has failed to do anything about it.[51]

**iv. Consumers desire meat and poultry products from animals raised without antibiotics and require accurate labeling in order to identify such products.**

In March 2012, Consumer Reports, the world's largest independent product-testing organization, conducted a survey of 1,000 U.S. consumers to explore their views on meat and poultry raised with or without antibiotics.[52] The vast majority of respondents were "extremely" or "very" concerned about the role of the widespread use of antibiotics in creating new superbugs and negatively impacting the environment.[53] Moreover, 86% believed that they should be able to buy "antibiotic-free" meat at their regular grocery stores.[54] Of those polled who could not purchase "antibiotic-free" meat at their regular grocery store, 82% stated that they would buy antibiotic-free meat or poultry if it was available.[55] Further, 61% of respondents said that they would pay more for antibiotic-free meat or poultry.[56]

In response to consumer demands, grocery stores have taken notice. Most major grocery stores carry antibiotic-free meat and poultry.[57] Whole Foods sells *only* antibiotic-free meat and

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[50] *Id*.

[51] *Id.* See also Section V.c, *infra*.

[52] Ex. BB, *Meat on Drugs*, CONSUMER REPORTS (June 2012), at 3, http://www.consumerreports.org/content/dam/cro/news_articles/health/CR%20Meat%20On%20Drugs%20Report%2007-12b.pdf.

[53] *Id.* at 8.

[54] *Id.*

[55] *Id.* at 3.

[56] *Id.*

[57] *Id.*

poultry.[58] When given the choice, consumers actively refrain from supporting an industry that is negatively impacting public health and the environment.

The evidence makes clear that consumers want to exercise an important choice regarding products produced with antibiotics, one with massive implications for their and the public's health generally. However, they are prevented from doing so because the current labeling practices do not require meat producers to distinguish between those products produced with antibiotics and those produced without. There is no way to tell the difference. Because current labeling regulations fail to require disclosure of these material facts, and in fact mislead consumers as described below, they directly frustrate consumer choice regarding an issue critical to individual and public health.

**b. <u>Legal Background and Standards</u>**

**i. FSIS is statutorily mandated to ensure safe meat and poultry products as well as accurate labeling.**

FSIS "is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[59] More specifically, FSIS is "responsible for ensuring the truthfulness and accuracy in labeling of meat and poultry items."[60] By its own internal documents, FSIS stresses that according to the Federal Meat Inspection Act ("FMIA") and the Poultry Products Inspection Act ("PPIA"), the "essentials of [its] job" is to verify that meat and poultry products are "(1) wholesome, (2) not adulterated, (3)

[58] See Ex. CC, *Our Meat: No Antibiotics, Ever*, http://www.wholefoodsmarket.com/blog/whole-story/our-meat-no-antibiotics-ever-0 (last visited March 10, 2013).

[59] Ex. DD, *About FSIS*, FOOD SAFETY INSPECTION SERVICE, http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Nov. 28, 2012). See also 21 U.S.C. § 602; 21 U.S.C. §§ 451-452.

[60] Ex. EE, *Meat and Poultry Labeling Terms*, FOOD SAFETY INSPECTION SERVICE, http://www.fsis.usda.gov/FACTSheets/Meat_&_Poultry_Labeling_Terms/index.asp (last visited Nov. 28, 2012). See also 21 U.S.C. § 602; 21 U.S.C. §§ 451-452.

properly marked/labeled, and packaged."[61] By statutory mandate, FSIS must ensure, for the "protection of the public," that no meat or poultry that is offered for sale in interstate commerce is misbranded – that is, meat and poultry packaging must not contain labels that are "false or misleading in any particular."[62] A label may be misleading not only because of what it says, but also because of what it fails to reveal.[63]

FSIS currently does not regulate antibiotic labeling for meat and poultry products, except that it allows producers to voluntarily use a "No Antibiotics Added" label on red meat and poultry if sufficient documentation is provided by the meat producer to FSIS demonstrating that the animals were raised without antibiotics.[64] Meat producers can also pay to have the USDA Agricultural Marketing Service verify this claim, in which case they can put "USDA Process Verified" on the label. FSIS does not currently require meat producers to label their products if their animals are raised using antibiotics, which allows such use to go undetected by unsuspecting consumers who rely on proper labeling to make purchasing decisions.

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[61] Ex. FF, *FSIS as a Public Health Regulatory Agency: FSIS Statutes and Your Role*, FOOD SAFETY INSPECTION SERVICE, at 2, http://www.fsis.usda.gov/PDF/PHVt-Statutes_Role.pdf (last visited Nov. 28, 2012); 21 U.S.C. § 602; 21 U.S.C. §§ 451-452.

[62] 21 U.S.C. §§ 601(n)(1), 602, 607(c) (Federal Meat Inspection Act); 21 U.S.C. §§ 451-452, 453(h)(1), 457(b) (Poultry Products Inspection Act). See also 9 C.F.R. § 317.8; § 381.129. Note that the false or misleading statements on labels do not have to be material to be actionable, in line with the public policy underlying the FMIA. Ex. GG, *U.S. v. Jorgensen*, 144 F.3d 550, 559 (8th Cir. 1998) ("Congress has determined that the companies and people engaged in the food business have an *affirmative duty* to insure that the food they sell to the public is *safe* and *properly labeled*.") (emphasis added).

[63] Ex. HH, *Grocery Mfrs. of America, Inc. v. Department of Public Health*, 379 Mass. 70, 76 (1979) (finding identical language "misleading in any particular" in state statute pertaining to the inspection and sale of food to include "an omission of fact as well as an express misstatement of fact").

[64] 21 U.S.C. §§ 601(n)(1), 602, 607(c) (Federal Meat Inspection Act); 21 U.S.C. §§ 451-452, 453(h)(1), 457(b) (Poultry Products Inspection Act). See also 9 C.F.R. § 317.8; § 381.129.

### ii. FSIS must ensure that meat and poultry labeling does not exacerbate an ongoing violation of the FDCA.

Any standards established under the FMIA and PPIA must be harmonized with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 310, et seq., ("FDCA") which also prohibits "the introduction or delivery for introduction into interstate commerce of any food…that is adulterated or misbranded."[65] Under the FDCA, FSIS and FDA have a shared responsibility to protect the public by "assuring a safe meat and poultry supply," and both regulate animal drugs.[66]

All antibiotics, including those used in animal feed at subtherapeutic levels, are "new animal drugs" under the FDCA. According to the FDCA, "a food shall be deemed to be adulterated if it bears or contains a new animal drug (or conversion product thereof) that is unsafe within the meaning of section [360b]."[67] Section 360b regulates the approval and continued use of animal drugs. Safety determinations for new animal drugs require the FDA to evaluate both human and animal health. According to the definitions section of the FDCA, "the term safe, as used in… sections 409, 512 [§ 360b], 571, 721, has reference to the health of man or animal."[68]

[65] 21 U.S.C. § 457(b); 21 U.S.C. § 607(c); 21 U.S.C. § 331.

[66] Ex. II, excerpt from FDA Directive 73171.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, 5-6 (H.H.S. 2005), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm113433.pdf.

[67] 21 U.S.C. § 342.

[68] 21 U.S.C. § 321(u).

## V. ARGUMENTS IN SUPPORT OF REQUESTED ACTION

### a. Consumers are confused and misled by current antibiotic labeling on meat and poultry products.

#### i. Current labeling practices are convenient to producers but provide no meaningful information to consumers.

As FSIS policy currently stands, consumers are forced to rely on voluntary, unverified labeling claims to determine how a producer raises animals used for food. The power is all in the hands of the producers, who, unless they raise their animals without antibiotics, have little incentive to tell customers the truth about their production practices or potential health risks of those practices. Mandatory labeling would shift this balance of power back into the hands of consumers, whose informed market demands for antibiotic-free meat would in turn spur producers to adopt antibiotic-free production methods, thereby reducing or eliminating the threat to public health, to meet the growing demand.

#### 1. Current labels are confusing, contradictory, and downright misleading.

The current voluntary labeling scheme certainly has not stopped meat producers from labeling their products however they see fit – even if it means that consumers have no idea what they are buying. In a Consumer Reports study of 136 supermarkets in 23 states, researchers found that meat producers currently use a wide array of labels to indicate their use (or lack thereof) of antibiotics, such as "never ever given antibiotics," "humanely raised on family farms without antibiotics," "natural," "antibiotic-free," "no antibiotic residues," and "no antibiotic growth promotants."[69] Although some of these claims are largely baseless, consumers rely on them to make what they think are better food choices. "Natural" means only that the product contains no artificial ingredients or added color and is minimally processed, but this label claim

[69] *Meat on Drugs*, CONSUMER REPORTS (June 2012), note 48 at 3.

has no bearing on antibiotic usage.[70] "Antibiotic-free" and "no antibiotic residues" are not USDA-approved terms for use on meat and poultry labels, but since there is currently no meaningful way to police the unauthorized use of these terms, meat producers have no reason not to use them.[71] Similarly, the label "no antibiotic growth promotants" has not been approved for use by the USDA and is even more misleading, since animals may still have been fed subtherapeutic levels of antibiotics for the purpose of disease prevention.[72] This label was found on pork products under the Farmland brand in three grocery stores owned by Kroger.[73]

These findings clearly demonstrate the variability and inherent confusion currently existing in the marketplace for meat and poultry products. Federal precedent has confirmed that the variety of labels currently in the marketplace – which mean different things to different people and remain unregulated – is inherently confusing to customers.[74] Meat producers have no incentive to provide truthful, meaningful information to consumers unless they do not feed their animals subtherapeutic levels of antibiotics. As evidenced in Consumer Reports' "Meat on Drugs," meat producers who use antibiotics try to capitalize on consumers' willingness to pay more for meat that comes from animals who have not been fed subtherapeutic levels of antibiotics by providing confusing labels on their packages.[75] For instance, researchers found a "no antibiotic residues" label on pork products in some stores – a claim which Consumer Reports found was potentially "very confusing."[76] Indeed, "[a]ntibiotics can be heavily used in the

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[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*at 21.

[74] See Section V.a.i.2 below.

[75] *Meat on Drugs,* CONSUMER REPORTS (June 2012), at 3, 18-21.

[76] *Id.* at 21.

growing process for pigs and chickens, but must be withdrawn for a period of days or weeks prior to slaughter, so that residue levels are below FDA tolerance thresholds. Technically, meat could be free of antibiotic residue despite the earlier use of antibiotics."[77] Without mandatory labeling requirements, meat producers simply will never admit openly and clearly through their packaging that they are regularly feeding their animals antibiotics. In turn, until labeling requirements are made mandatory and regulated by FSIS, consumers will remain incapable of ensuring their own safer purchases and incapable of ensuring they are not supporting meat production practices that are contributing to this looming public health crisis.

Given the widespread misrepresentations currently found in the market, with no enforcement mechanism to address them, FSIS must take comprehensive and preventative action as proposed in this petition to fulfill its statutory mandate to prevent misleading labeling of meat and poultry products in the marketplace. Enabling meat producers to self-police clearly is not working. The most efficient and effective way to remedy the current pervasive misleading labeling in the marketplace – both in labels that meat producers are using and in the lack of any label at all – is to require uniform disclosure of antibiotic usage on all meat and poultry packaging so that consumers can make informed food choices.

**2. The current labeling scheme is so misleading that it provides grounds for false advertising claims under the Lanham Act.**

Given the multitude of labels pertaining to antibiotic usage utilized by various meat producers – each of which means a different thing to each producer – it is no wonder that the current labeling scheme has led to litigation for false advertising. Indeed, in 2008, Sanderson Farms, Inc. and Perdue Foods sued Tyson Foods for using the terms "Raised Without Antibiotics" and "Raised Without Antibiotics that impact antibiotic resistance in humans,"

[77] *Id.*

claiming such usage constituted false advertising under the Lanham Act.[78] The basis of their claims was that Tyson was administering antibiotics before eggs hatched, so their chickens were not "raised without antibiotics," and they claimed the second term was simply confusing and misleading.[79] Plaintiffs administered a consumer survey, which confirmed that consumers assumed that "Raised Without Antibiotics" meant that Tyson used no antibiotics in its chicken at any point. The survey also confirmed that consumers disregarded the second label because they did not know what it meant.

Ultimately, the Court agreed that Tyson's labels constituted false advertising, finding that "consumers are being misled by Tyson's advertisements proclaiming that its chicken is 'Raised Without Antibiotics.' Based largely on Plaintiffs' consumer survey, this Court also finds that the qualified language 'Raised Without Antibiotics that impact antibiotic resistance in humans' is not likely to be understood by a significant portion of the consumer public."[80] The Court also focused on data showing that nine out of ten consumers considered it important to have antibiotic-free chicken.[81] The data actually showed that this factor was the *second most important* claim that consumers looked for when shopping for chicken.[82]

Whenever the question has been asked, consumers have confirmed that they want meat products that come from animals raised without antibiotics. They also agree that the current labeling scheme is misleading. Consumers deserve more than a semi-educated guess, especially when it comes to the safety of their food and when their food choices have a direct impact on a unique and looming threat to public health. This is especially the case when consumers are up

[78] See Ex. JJ, *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 547 F. Supp. 2d 491 (D. Md. 2008).

[79] *Id.* at 492.

[80] *Id.*

[81] *Id.*

[82] *Id.*

against an industry that profits from consumer confusion. Absent lawsuits filed against every meat producer for violations of the Lanham Act, this misleading labeling scheme will never be fixed – unless, of course, FSIS takes matters into its own hands, as it should and as it is statutorily mandated to do.

**ii. Failure to label meat and poultry that comes from animals raised with subtherapeutic antibiotics prevents consumers from obtaining information necessary to make informed decisions.**

**1. Consumers are entitled to information about farming practices that negatively impact human health.**

Currently, a consumer may pick up two packages of meat at the grocery store – one containing meat that comes from an animal fed subtherapeutic levels of antibiotics and the other containing meat that comes from an animal raised free from antibiotics – and may reasonably conclude that there is no difference between the meat because there is no reliable label to tell her otherwise. Without a required label, this consumer cannot make an informed purchase decision. That is, she has no reliable means to ensure that she is buying the safer product, and thereby only supporting meat producers who are not contributing to a rampant public health crisis through irresponsible antibiotic usage. She may have every intention to buy only meat that comes from animals raised without antibiotics, but has been rendered powerless to do so by a lack of meaningful label regulation.

As discussed above, the current labeling scheme (that is, a voluntary and self-policed regulatory scheme) provides little information to consumers, and what it does provide may be downright false. Either way, without a uniform set of mandatory guidelines regarding labeling for antibiotic usage, consumers are misled and confused, and FSIS must act promptly to dispel

this confusion.[83] Current labels (or lack thereof) signal to the consumer that there is no difference between the two packages of meat in her hand, when in fact the two are materially different.[84] Indeed, one package may have come from a meat production facility which is directly contributing to a growing public health crisis while the other may have come from animals who have not been raised on subtherapeutic doses of antibiotics. The consumer must rely on the meat producers to tell her how the animals were raised – and consumers can be sure that no meat producer will voluntarily display on its packages that its meat came from animals raised with antibiotics. Consumers rely on FSIS to require such labeling.

Recent studies have shown that consumers are absolutely concerned about issues related to the use of antibiotics in animal feed – including the potential creation of "superbugs," unsanitary and crowded conditions for livestock, human consumption of antibiotic residue, and environmental effects due to agricultural runoff containing antibiotics, and they have a right to support particular industries and producers through their purchasing decisions.[85] As mentioned above, in response to a Consumer Reports survey of U.S. consumers, the vast majority of respondents were "extremely" or "very" concerned about the role of the widespread use of antibiotics in creating new superbugs and negatively impacting the environment.[86] Given the risks to humans of the use of subtherapeutic doses of antibiotics in animal feed, and heightened consumer concern about these risks, any reasonable consumer would be justified in supporting

[83] See *Grocery Mfrs. of America, Inc.*, 379 Mass. at 76 (finding language "misleading in any particular" in state statute pertaining to the inspection and sale of food to include "an omission of fact as well as an express misstatement of fact").

[84] See Ex. KK, *Restatement (Second) of Torts* § 538(a) (1977) (a matter is material if "a reasonable man would attach importance to its existence or nonexistence in determining his choice of action" or "the maker of the representation knows or has reason to know" that the recipient is likely to consider "the matter as important.")

[85] *Meat on Drugs*, CONSUMER REPORTS (June 2012), note 48 at 8.

[86] *Id.*

only those producers that do not contribute to the proliferation of the growth of superbugs, by specifically seeking meat that is raised without antibiotics. Consumers have the right to be provided with clear, consistent information about antibiotic usage in their meat. In other words, consumers should not be forced to contribute to an industry that they do not support simply because they have no consistent, accurate way of differentiating between meat that comes from animals raised with antibiotics from that which does not. The current system thwarts consumers' abilities to make sound choices about what they are willing to pay for, and, ultimately, what they are willing to support with their wallets.

Ultimately, that consumers are prevented from making decisions that have far-reaching health consequences further establishes FSIS's statutory and legal mandate to correct materially misleading labeling. FSIS is required to shield consumers from a labeling system that fails to inform them that their purchase contributes to significant public health risks, and is therefore inherently misleading. ALDF's proposed regulations will require producers to accurately represent their meat production methods to consumers, so that meat producers will no longer be able to profit from consumer confusion in the marketplace.

**2. Recent studies suggest there is a material difference between meat that comes from animals raised with antibiotics and meat that comes from animals that are not raised with antibiotics.**

In light of the consumer studies above and related threat to public health, consumers should have the right to choose the kind of farming practices they are willing to contribute to – which can only happen if meat producers are required to label their meat accordingly. Consumers should also have the right to choose whether they want to buy meat that comes from animals raised with antibiotics because recent studies suggest there is a material difference in the meat itself. Indeed, scientific evidence now suggests that meat that comes from animals raised

with antibiotics contains more antibiotic-resistant superbugs *in the meat itself* than meat that comes from animals that are antibiotic-free.[87] In one study performed by Consumer Reports, ground turkey that came from birds fed subtherapeutic levels of antibiotics was shown to contain bacteria that was more likely to resist drugs that could help cure illness than ground turkey that was antibiotic-free.[88] Thus, the two packages of meat in a consumer's hands are, in fact, materially different in a way that could have devastating medical consequences to the consumer, yet she remains completely uninformed of this difference because no label exists to inform her. That is, consumers who purchase meat from animals raised with subtherapeutic antibiotics are more likely to be exposed to antibiotic-resistant bacteria when they handle that meat – and, in turn, are much more likely to suffer adverse health consequences due to that exposure.[89] FSIS must act promptly to dispel this confusion.[90]

As discussed above, FSIS's mission includes "ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[91] This mandate to keep the food supply safe means that FSIS should not be allowing meat producers to experiment on consumers while scientific developments further confirm what we already know to be true. Recent evidence indicating that consumers are exposed to

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[87] *Superbugs Invade American Supermarkets,* ENVIRONMENTAL WORKING GROUP (April 2013), http://www.ewg.org/meateatersguide/superbugs/; Ex. LL, *Consumer Reports Investigation: Talking Turkey,* CONSUMER REPORTS (June 2013), http://www.consumerreports.org/cro/magazine/2013/06/consumer-reports-investigation-talking-turkey/index.htm.

[88] *Consumer Reports Investigation: Talking Turkey,* CONSUMER REPORTS (June 2013).

[89] See Section IV.a.iii above.

[90] See *Grocery Mfrs. of America, Inc.,* 379 Mass. at 76 (finding identical language "misleading in any particular" in state statute pertaining to the inspection and sale of food to include "an omission of fact as well as an express misstatement of fact").

[91] *About FSIS,* FOOD SAFETY INSPECTION SERVICE, *available at* http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Nov. 28, 2012). See also 21 U.S.C. § 602; 21 U.S.C. §§ 451-452.

heightened levels of antibiotic-resistant bacteria when they buy meat that comes from animals raised with antibiotics should be sufficient to move FSIS to caution consumers about their purchasing decisions.[92] With so much on the line, FSIS should choose to be precautionary rather than reactionary when it comes to consumer safety.

**iii. Because of the effects of subtherapeutic antibiotic use on animal and human health, the lack of labeling exacerbates an ongoing violation of the FDCA.**

The text of § 360(b) of the FDCA itself bears out Congressional concern for the health of both humans and the target animals of veterinary drugs. Grounds for approving and revoking new animal drug 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."[93] Further, in its own interpretation of § 360(b), the FDA has concluded that Congress has placed human and animal health central to the new animal drug approval analysis.[94]

The use of subtherapeutic antibiotics is creating a public health crisis that stands to gravely undermine the effectiveness of antibiotics in treating bacterial infections in humans. Undoubtedly, such a threat renders the use of antibiotics in animal feed unsafe to humans and therefore constitutes a violation of the FDCA. Furthermore, antibiotic use in animals compromises animal health in two ways. First, it increases the level of resistant bacteria in the animals themselves, which directly affects animal health. Subtherapeutic antibiotic use also

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[92] *Superbugs Invade American Supermarkets*, ENVIRONMENTAL WORKING GROUP (April 2013); *Consumer Reports Investigation: Talking Turkey*, CONSUMER REPORTS (June 2013).

[93] 21 U.S.C. § 360b(d)(2)(B); see also Ex. MM, *Stauber v. Shalala*, 895 F.Supp. 1178, 1192 (W.D. Wis. 1995) (citing both human and animal health as a factor for FDA determination of animal drug safety).

[94] See, e.g., Ex. NN, Enrofloxacin for Poultry, 65 Fed. Reg. 64954 (Oct. 31, 2000) ("Accordingly, CVM must consider not only the safety of the new 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.").

enables famers to raise animals in high-density confinement to produce the highest output possible, with profound negative effects on animal welfare, as discussed above. As a result, agency approvals of the antibiotic overuse that seriously harms human and target animal health likely violate FDCA § 360(b).[95] By failing to provide consumers with the necessary information on labels to avoid contributing to farming practices that negatively impact both human and animal health, FSIS is exacerbating an ongoing violation of the FDCA.

**iv. FSIS is statutorily mandated to correct misinformation in the market.**

Because FSIS does not currently require meat producers to disclose to consumers whether the meat and poultry products they are purchasing originated from animals that were fed subtherapeutic levels of antibiotics, consumers are confused, misled, and ultimately unable to make informed decisions. Omission of these material facts as to the wholesomeness and origin of these meat products forces consumers to rely on voluntary, unverified labeling claims to determine how a producer raises the animals used for food. Moreover, by purchasing meat that comes from animals raised with subtherapeutic levels of antibiotics, consumers are contributing to an industry that they may not wish to support, simply because they are denied material information necessary to make informed purchasing decisions. This blatant lack of disclosure, particularly when coupled with the burgeoning use of unregulated antibiotics claims, constitutes "misbranding" and "mislabeling," is "misleading," and violates the letter and spirit of the PPIA, FMIA, and the FDCA. Therefore, pursuant to section 553(e) of the APA, which provides interested persons the right to petition federal agencies to amend agency rules, ALDF requests FSIS to expeditiously adopt the petition's suggested amendments to the poultry and meat product

[95] See *NRDC v. U.S. FDA*, 884 F. Supp. 2d 127 (2012).

labeling regulations in order to harmonize USDA regulations with the enabling statutes' blatant prohibition on "misleading" labels and "misbranded" products.

**b. <u>FSIS is already well aware that regulation of labeling pertaining to antibiotic usage is necessary.</u>**

The relief sought by ALDF in this petition is not novel to the USDA. Indeed, the USDA already contemplated regulating antibiotics claims and disclosures on meat labels a decade ago, when the Agency proposed regulations that would have streamlined antibiotics claims and standards on meat and poultry labels.

Specifically, in 2002, in an effort to address the growing concern among American consumers over the human health consequences from the widespread misuse of antibiotics in industrial animal agriculture, the USDA's Agricultural Marketing Service ("AMS") proposed establishing minimum requirements for common production and marketing claims relating to the use of antibiotics.[96] AMS justified the need for uniform antibiotics claims, recognizing that, "some consumers prefer meat products from animals that have not been fed and/or treated with antibiotics and some producers are willing to provide additional assurances of compliance with regulatory requirements[.]"[97] In light of consumer demand for greater disclosure on meat and poultry labels, the Agency proposed various classes of antibiotics claims with accompanying standards, including: "no antibiotics used" or "raised without antibiotics" for livestock that have never received antibiotics from birth to harvest; and "no subtherapeutic antibiotics added" or "not fed antibiotics" for livestock that have not been fed subtherapeutic levels of antibiotics, but may have received treatment for illness.[98]

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[96] See Ex. OO, United States Standards for Livestock and Meat Marketing Claims, 67 Fed. Reg. 79552, 79552-56 (Dec. 30, 2002).

[97] *Id.* at 79554.

[98] *Id.*

In effect, these proposed labeling standards would have incentivized producers not to administer subtherapeutic levels of antibiotics so they could advertise the antibiotic-free claims and capitalize off the growing market demand for antibiotic-free meat and poultry. Moreover, by providing a standard for verified antibiotic-free claims, by default, consumers could easily deduce which products came from animals routinely fed antibiotics simply by virtue of the conspicuous lack of a consistent antibiotic-free label. Ultimately, the proposed regulations were withdrawn. Despite what meat producers prefer, and the ease to FSIS of keeping labeling requirements voluntary, FSIS is statutorily required to institute change in labeling requirements, as explained above.

**c. <u>Recent decisions regarding antibiotic usage means federal agencies cannot ignore their statutory mandates to take necessary action to protect the public health.</u>**

Two recent court rulings specifically address statutory obligations to protect public health by regulating the misuse of antibiotics in industrial animal agriculture. In *Natural Resources Defense Council v. U.S. Food and Drug Administration*, a federal magistrate judge in the Southern District of New York ruled that the FDA may not continue to evade its statutory directive to institute withdrawal proceedings for the subtherapeutic use of medically important antibiotics, namely penicillin and tetracyclines, in food-producing animals due to the proven and well-documented health risks associated with such use.[99]

At issue in this proceeding was the FDA's thirty-year refusal to hold hearings on the withdrawal of penicillin and tetracyclines in animal feed, despite the FDA's unwavering position over this same time span that widespread use of certain antibiotics in livestock for purposes other

[99] See *NRDC v. FDA*, 884 F. Supp. 2d 127 (2012), (hereinafter "NRDC I"); Ex PP, *NRDC v. FDA*, 872 F. Supp. 2d 318 (2012), (hereinafter "NRDC II").

than disease treatment poses a threat to human health.[100] In 1977, the director of the Bureau of Veterinary Medicine (a division of the FDA now known as the Center for Veterinary Medicine ("CVM")) had issued notices of an opportunity for hearing ("NOOHs") following a decisive recommendation from a sub-committee of the FDA's National Advisory Food and Drug Committee "that FDA immediately withdraw approval for the subtherapeutic uses of penicillin, i.e., growth promotion/feed efficiency, and disease control," and "control the distribution of the tetracyclines through … a veterinarian's order to restrict their use."[101] Even though approximately twenty drug firms, agricultural organizations, and individuals requested hearings in response to the 1977 NOOHs, the Commissioner of the FDA never set a date for the hearings on the BVM's proposal to withdraw approval of the subtherapeutic use of penicillin and tetracyclines in food animals.[102]

Ultimately, the court ruled that the FDA's failure to initiate withdrawal proceedings for the subtherapeutic use of these drugs in accordance with the 1977 NOOHs violated the APA as "agency action unlawfully withheld or unreasonably delayed."[103] According to the Court, when the Director of the BVM "explicitly concluded that the drugs had not been shown to be safe [pursuant to Section 360(b) of the Federal Food, Drug, and Cosmetic Act]," such a conclusion was the statutory trigger for the FDA to initiate withdrawal proceedings.[104] As such, the Court ordered the FDA or the Director of the CVM (formerly the BVM) to hold withdrawal hearings

[100] *NRDC I*, 884 F. Supp. 2d 127 (2012) at *131.

[101] *Id.* at *133.

[102] *Id.* at *134.

[103] *Id.* at *137 (citing 5 U.S.C. § 706(1), the section of the APA which authorizes the court to grant plaintiffs relief if they can show that an agency failed to take legally required discrete action).

[104] *Id.* at *148.

for the subtherapeutic use of penicillin and tetracyclines.[105] Moreover, if the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order.[106]

A little over two months after this ruling was announced, the Court issued a second opinion on a related action involving the FDA's denial of two citizen petitions, filed in 1999 and 2005, that requested the agency to withdraw the subtherapeutic uses of "medically important" antibiotics (i.e., drugs that are also used to treat humans).[107] The Court concluded that the FDA acted "arbitrarily and capriciously," in violation of the APA,[108] when it denied both citizen petitions.[109] In the Court's words, "[i]n the course of this litigation, the [a]gency has conceded that 'the phenomenon of antimicrobial resistance exists, [that] antimicrobial resistance poses a threat to public health, [and that] the overuse of antimicrobial drugs in food-producing animals can contribute to the development of antimicrobial resistance.'"[110] What confounded the Court, however, was that "[f]or over thirty years, the [FDA] has been confronted with evidence of the human health risks associated with the widespread subtherapeutic use of antibiotics in food-

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[105] *Id.* at *149.

[106] *Id.*

[107] *NRDC II*, 872 F. Supp. 2d 318 (2012) at *324. "On March 9, 1999, four of the named Plaintiffs, CSPI, FACT, Public Citizen, and UCS, as well as the Environmental Defense Fund, submitted a Citizen Petition to the FDA requesting that the agency 'rescind approvals for subtherapeutic uses in livestock of any antibiotic used in (or related to those used in) human medicine.' " *Id*. "On April 7, 2005, named Plaintiff DCS, as well as the Environmental Defense Fund, the American Academy of Pediatrics, and the American Public Health Association, filed a Citizen Petition with the FDA 'to withdraw approvals for herdwide/flockwide uses of [certain antibiotics] in chicken, swine, and beef cattle for purposes of growth promotion (including weight gain and feed efficiency) and disease prevention and control (except for non-routine use where a bacterial infection has been diagnosed within a herd or flock) [.]' " *Id.* at *326.

[108] 5 U.S.C.(2)(A) ("The reviewing court shall 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.").

[109] *NRDC II*, 872 F. Supp. 2d 318 (2012) at *324. See also, *e.g.*, *id.* at *338 ("Denying the Petitions on the grounds that it would be too time consuming and resource-intensive to evaluate each individual drug's safety, and withdraw approval if a drug was not shown to be safe, is arbitrary and capricious.")

[110] *Id.* at *340 (citing Memorandum of Law in Support of the Government's Motion for Summary Judgment on Plaintiff's First Supplemental Complaint, *NRDC II*, 872 F. Supp. 2d 318 at 2).

producing animals, and, despite a statutory mandate to ensure the safety of animal drugs, the [a]gency has done shockingly little to address these risks."[111]

In holding that the FDA's proffered grounds for denying the citizen petitions were arbitrary and capricious, the Court remanded the matter back to the FDA to more extensively "evaluate the safety risks of the petitioned drugs and either make a finding that the drugs are not shown to be safe or provide a reasoned explanation as to why the [a]gency is refusing to make such a finding."[112] While the Court made certain that its order was not compelling the FDA to reach any particular conclusion, the Court found that the FDA could not, without more, continue to base its refusal to regulate widespread antibiotic use on its two long-held defenses: first, that the agency is hobbled by the "time and expense" associated with thoroughly investigating the safety of antibiotics and the withdrawal proceedings required for drugs determined to be unsafe; and second, that the FDA had administered "non-binding voluntary" guidelines to promote "judicious" use of antibiotics in food-producing animals, which it argued would essentially achieve the same ends as formal withdrawal proceedings.[113] Rather, through these proceedings, the parties agreed that, "using medically important antimicrobial drugs for production purposes *is not in the interest of protecting and promoting the public health*," which required FDA action in accordance with the FDA's authorizing statute.[114]

Though these cases dealt with an entirely different federal agency, the message is clear: federal agencies must abide by their statutory mandates or face an order to do so through the court system. To that end, agencies may not "substitute proposed voluntary measures … for the

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[111] *Id.* at *342.

[112] *Id.*

[113] *Id.* at *337.

[114] *Id.* at *340 (emphasis added).

measures mandated by statute."[115] More specifically, in *NRDC II*, the court explained that, "[i]n responding to a citizen petition, an agency's 'reasons for action or inaction must conform to the authorizing statute.'"[116] In that case, the court found that the FDA failed to conform to its authorizing statute – the FDCA – when it did not focus its inquiry on whether antibiotics were safe and effective in determining whether withdrawal of its approval of those drugs was appropriate.[117]

Similarly, in these circumstances, FSIS must conform with its authorizing statutes – the PPIA and FMIA – which state that FSIS must ensure for the "protection of the public," that no meat or poultry that is offered for sale in interstate commerce is misbranded – that is, meat and poultry packaging must not contain labels that are "false or misleading in any particular."[118] Accordingly, FSIS must take action and adopt the recommendations set forth in this petition to eliminate from the marketplace labels that are false and misleading. The current voluntary labeling scheme, which itself is severely inadequate (as discussed in Section V.a.i above), does not fulfill FSIS's statutory mandate since FSIS may not "substitute proposed voluntary measures…for the measures mandated by statute."[119] Rather, FSIS is statutorily required to take action to affirmatively cure the misleading labeling of meat and poultry products.[120] The recent

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[115] *Id.* (citing *NRDC v. EPA*, 595 F. Supp. 1255, 1261 (S.D.N.Y. 1984) ("It is not an agency's prerogative to alter a statutory scheme even if its assertion is as good or better than the congressional one.")).

[116] *Id.* at *337 (quoting *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007)).

[117] *Id.*

[118] 21 U.S.C. §§ 601(n)(1), 602, 607(c) (Federal Meat Inspection Act); 21 U.S.C. §§ 451-452, 453(h)(1), 457(b) (Poultry Products Inspection Act). See also 9 C.F.R. § 317.8; § 381.129.

[119] *Id.* at *340 (citing *NRDC v. EPA*, 595 F. Supp. 1255, 1261 (S.D.N.Y. 1984) ("It is not an agency's prerogative to alter a statutory scheme even if its assertion is as good or better than the congressional one.")).

[120] 21 U.S.C. §§ 601(n)(1), 602, 607(c) (Federal Meat Inspection Act); 21 U.S.C. §§ 451-452, 453(h)(1), 457(b) (Poultry Products Inspection Act). See also 9 C.F.R. § 317.8; § 381.129.

cases brought against the FDA illustrate that absent such action in response to this petition, a court may find that FSIS acted arbitrarily and capriciously, in violation of the APA.[121]

## VI. CONCLUSION

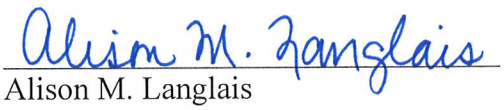
As discussed herein, consumers trust and rely on product packaging to learn about the safety and wholesomeness of their food products as well as to make choices that will impact public health in general. FSIS has failed consumers by not requiring meat producers to provide information about antibiotic use, which poses a unique threat to public health, on product packaging. Such a lack of required disclosure perpetuates current mislabeling in the market as well as the potentially devastating abuse of antibiotics by the poultry and meat industry, while the current voluntary antibiotic labeling scheme has proven misleading by way of the myriad of disparate labels currently used in the marketplace, survey evidence illustrating that these labels are inherently confusing, and federal precedent that confirms some of these labels constitute "false advertising" under the Lanham Act. Instituting the mandatory labeling scheme that Petitioner proposes is statutorily mandated and required to protect public health by allowing consumers to make fully informed decisions when they purchase meat and poultry products. FSIS must promulgate the proposed regulations for all of the reasons discussed herein.

[121] *NRDC II*872 F. Supp. 2d 318 (2012) at *342. See also, *e.g.*, *id.* at *338.

Respectfully submitted,

Animal Legal Defense Fund

By its attorney,



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