IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

LYSTN, LLC d/b/a ANSWERS™ PET FOOD, Plaintiff,	:	Civ. No. 19-cv-1943
v.	:	
FOOD AND DRUG ADMINISTRATION	:	
ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS	:	
COLORADO DEPARTMENT OF AGRICULTURE	:	
KATE GREENBERG, INDIVIDUALLY AND OFFICIALLY IN HER CAPACITY AS COMMISSIONER OF THE COLORADO DEPARTMENT OF AGRICULTURE	:	
LAUREL HAMLING, INDIVIDUALLY AND OFFICIALLY IN HER CAPACITY AS FEED PROGRAM ADMINISTRATOR FOR THE COLORADO DEPARTMENT OF AGRICULTURE	:	
SCOTT ZIEHR, INDIVIDUALLY AND OFFICIALLY IN HIS CAPACITY AS FEED PROGRAM REGULATORY ADMINISTRATOR FOR THE COLORADO DEPARTMENT OF AGRICULTURE	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendants.	:	

COMPLAINT

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I. NATURE OF ACTION

1. This is a civil action for declaratory and injunctive relief. Lystn, LLC d/b/a ANSWERS™ Pet Food ("Plaintiff") challenges the Food and Drug Administration's ("FDA") decision to enforce and lawfulness of their actions, through its own actions and with the cooperation of the Association of American Feed Control Officials ("AAFCO") – a "voluntary membership association of local, state and federal agencies charged by law to regulate the sale and distribution of animal feeds…", Colorado's Department of Agriculture – a participating state department in its official capacity by and through the actions of Kate Greenberg (Commissioner), Laurel Hamling (Feed Program Administrator), and Scott Ziehr (Co-Administrator Regulatory Administrators of the Feed Program), a nationwide zero-tolerance standard for *Salmonella* presence in pet food that is unsupported by science and ultra vires of powers properly delegated to it by Congress.

II. PREDICATE BACKGROUND

2. On November 6, 2006, bags of tainted wheat gluten from Xuzhou Anying Biologic Technology Development Company in China are imported to the United States from a Chinese textile company. That same month, a Canada-based company begins to use the tainted wheat gluten at its plants in the U.S. states of Kansas and New Jersey.

3. By December of 2006, numerous unconfirmed reports of sick pets associated with the tainted food begin to surface[1], yet the maker of the tainted food waits until February 20, 2007

[1] *Byron, Katy (April 5, 2007). "Officials say 38 Oregon pet deaths could be tied to recall". CNN. Retrieved 2007-04-11.*

to acknowledge the subject complaints, (with the Chief Financial Officer thereof selling roughly half his stock in the company less than a week later and prior to recall).[2]

4. With as many as 1 in 6 pets dying after eating the food made with the tainted wheat gluten, its maker began an investigation into a "possible problem" with its food on March 2, 2007,[3] - sending samples for testing to both Cornell University and a New York state based testing facility mid-month.[4] Then, on March 16, 2007 the maker of the tainted food issued a VOLUNTARY U.S. nationwide recall for dog and cat foods produced at two of its facilities between December 3, 2006, and March 6, 2007.[5]

5. The initial recall comprised sixty million units of cuts and gravy-style food in pouches sold under nearly 100 brand names, including premium brands and private-label brands sold at nationwide chains.[6] While the recalled products represent just 1% of pet foods available in the U.S.[7] the recall is one of the largest in American history.[8] On March 21, 2007 the maker of the tainted food confirmed that it was the Chinese wheat gluten used to thicken and enrich the

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[2] *Wade McCormick, Lisa (April 11, 2007). "Menu Foods Executive Sold Shares Weeks Before Pet Food Recall". Consumer Affairs. Archived from the original on April 22, 2007. Retrieved 2007-04-11.*

[3] *Swaminathan, Nikhil (March 28, 2007). "Special Report: The Poisoning of Our Pets - Scientists and government agencies home in on the cause of more than 100 pet deaths from tainted food". Scientific American. Retrieved 2007-04-11*

[4] *"Lab Gets New Attention in Pet Food Case". Washington Post. April 1, 2007. Retrieved 2007-04-11; "FDA Pet Food Recall page". Retrieved 2007-04-11.*

[5] *"Menu Foods' initial recall press release". Archived from the original on 2007-04-11. Retrieved 2007-04-11; Associated Press (March 21, 2007). "Owners watching pets closely after food recall - At least 16 pet deaths tied to tainted food; vets flooded with worried calls". MSNBC. Retrieved 2007-04-11*

[6] *Bell, Kevin (March 19, 2007). "Menu Foods Fund Plunges After Recall of Dog, Cat Food (Update6)". Bloomberg News. Retrieved 2007-04-11.*

[7] *Mary Owen, Mary Ann Fergus (April 6, 2007). "Dog biscuits added to pet-food recall - Durbin seeks stricter oversight of industry". Chicago Tribune. Retrieved 2007-04-11*

[8] *Zezima, Katie (March 21, 2007). "Toll From Tainted Pet Food Is 14; F.D.A. Is Focusing on New Gluten". New York Times. Retrieved 2007-04-11*

gravy in the canned and pouched wet food products, and that the medical problems exhibited in test subjects included renal failure.[9]

6. Three days later, the voluntary recall was voluntarily expanded to include dozens of more cat and dog food products, including all varieties of 'cuts and gravy' type wet pet food in cans and pouches, in order to ensure pet stores removed any chance of contaminated batches reaching consumers.[10] Then, on March 30, 2007, the U.S. Food and Drug Administration (FDA) announced a possible source of the sicknesses, indicated by the presence of melamine, an industrial chemical, in wheat gluten imported from China. The FDA then prohibited the import of wheat gluten from a specific Chinese company and said that the contamination may be in dry pet foods as well.[11]

7. On April 4, 2007, the Chinese government refuses the FDA's requests to inspect facilities suspected of producing contaminated products.[12] Then, the next day it categorically denies any connection to the North American food poisonings to the *New York Times*, claiming they had no record of exporting any agricultural products that could have tainted the recalled pet foods, including the wheat gluten that has been the focus of the investigation. The general

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9 *"Pet Connection Food Recall Index". Archived from the original on 2007-03-28. Retrieved 2007-04-11*

10 *"ASPCA Press Release: ASPCA Advises Caution As Pet Food Recall Crisis Grows - Other Contaminants May Be Involved in the Menu Foods Recall". Archived from the original on 2007-05-13. Retrieved 2007-04-11*

11 *Weise, Elizabeth (March 30, 2007). "Nestlé Purina, Hills join pet food recall". USA Today. Retrieved 2007-04-11; (March 31, 2007). "Del Monte Pet Products Voluntarily Withdraws Specific Product Codes of Pet Treats and Wet Dog Food Products". Business Wire/Yahoo.com. Retrieved 2007-04-11; Press Release (March 31, 2007). "ALPO(R) Brand Prime Cuts in Gravy Canned Dog Food Voluntary Nationwide Recall - No Dry Purina Products Involved". PR Newswire. Archived from the original on April 9, 2007. Retrieved 2007-04-11; Henderson, Diedtra (April 3, 2007). "Was human food tainted too? - Suspect gluten went to plants that make products for people, FDA says". Boston Globe/Boston.com. Retrieved 2007-04-11.*

12 *Carboza, David (April 5, 2007). "China Says It Had Nothing to Do With Tainted Pet Foods". New York Times. Retrieved 2007-04-11.*

manager of the subject Chinese company also denied that they had exported any wheat gluten to North America, with the Chinese government telling the Associated Press they will "investigate."

8. Next, on April 9, 2007 scientists at University of California, Davis animal health laboratory confirmed that a "popular brand of pet food" submitted for testing by area veterinarians was contaminated with melamine, even though it is not on the list of recalled cat and dog foods.[13]

9. Once again, the next day the maker of the tainted food voluntarily expanded its voluntary recall to include foods manufactured at plants in Canada.

10. By April 11, 2007 there are more than 130 brands of dog and cat foods from five companies voluntarily recalled. Most of the foods are wet, though there are some dry foods and dog biscuits that are recalled as a precautionary measure even though no cases of poisoning from dry foods had yet been reported.

11. Nationwide, the tainted pet food crises had reached such a level of concern that on April 12, 2007 Senator Dick Durbin held Hearings before the United States Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. Therein, FDA officials admit that contaminated food was likely still on store shelves throughout the country and urged consumers to re-check the food they have in their possession.[14]

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[13] *Associated Press (April 10, 2007). "Canadian Pet Food Added to Recall List". Chicago Tribune. Archived from the original on March 20, 2007. Retrieved 2007-04-11.*

[14] *Abruzzese, Sarah (April 13, 2007). "Tainted Pet Food Is Said to Be Still on Shelves". New York Times. Retrieved 2007-04-13*

12. On April 23, 2007, China finally gave permission to FDA investigators to enter the country.[15]

13. The next day, the FDA announces that melamine has been found in the urine of hogs in North Carolina, California, and South Carolina; that farms in Utah, New York, and possibly Ohio had received contaminated feed. They had not yet determined if, beyond a small amount in California, any contaminated meat had reached the human food supply. The FDA also announces that it was now testing six common food ingredients – wheat gluten, corn gluten, cornmeal, soy protein, rice bran and rice protein concentrate – as a precaution.[16]

14. By April 25, 2007, FDA Officials traced the melamine responsible for pet deaths to two Chinese plants, which have been supplying American distributors since the Ssummer of 2006.

15. On April 26, 2007 the FDA announced that over 6,000 hogs had been quarantined on farms in California, New York, South Carolina, North Carolina, Utah, Kansas, Oklahoma, and Ohio. Additionally, the U.S. Department of Agriculture announced that the meat of 345 hogs that had eaten contaminated feed had entered the U.S. food supply, possibly via slaughterhouses in Kansas and Utah.

16. On April 26 and 27, 2007, several voluntary recalls were either expanded or issued for the first time as the FDA announces that of 750 samples of wheat gluten and products containing wheat gluten that 330 had tested positive for melamine contamination. Out of 85 samples of rice protein concentrate and products made with it, 27 were contaminated.

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[15] *ebuck, Karen (April 25, 2007). "FDA expands probe into tainted pet food". Pittsburgh Tribune-Review. Archived from the original on October 21, 2008. Retrieved 2007-04-25.*

[16] *Weise, Elizabeth (May 28, 2007). "Judge tells pet food reps to back off". USA Today. Retrieved 2007-06-09.*

17. On April 28, 2007 the Chicago Tribune reports that, according to California state officials, approximately 45 state residents consumed pork from hogs that had been fed melamine-contaminated feed. Then, on April 30, 2007 the FDA and the United States Department of Agriculture (USDA) issue a joint press release stating that contaminated feed was used at approximately 38 chicken farms in Indiana in early February and that all fed broiler chickens have been processed.[17]

18. Then, on May 9, 2007 (with approximately 20 million chickens intended for human consumption found to also be potentially tainted), Officials from the USDA and FDA testify in front of the United States House of Representatives Committee on Agriculture as the voluntary recalls and reports of tainted food intended for human consumption multiply.

19. In the wake of this national crisis (one which implicated not only the health and safety of pets but also the vulnerability of our food supply fed similarly tainted feed) a united Congress, (having held Hearings and the testimony of various officials from the FDA), unanimously passed (in both the House and Senate) 21 U.S.C. **§** 2102 which mandated:

> **(a) PROCESSING AND INGREDIENT STANDARDS** Not later than 2 years after September 27, 2007, the Secretary of Health and Human Services (referred to in this chapter as the "Secretary"), in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish:
>
> **(1)** processing standards for pet food; and
>
> **(2)** updated standards for the labeling of pet food that include nutritional and ingredient information.

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[17] *"FDA and USDA Investigate Tainted Animal Feed". Food and Drug Administration (United States). April 30, 2007. Retrieved 2007-05-02; "Joint Update: FDA/USDA Trace Adulterated Animal Feed to Poultry". USDA and U.S. Food and Drug Administration. April 30, 2007. Retrieved 2007-05-01*; *"FDA/USDA Joint News Release: Scientists Conclude Very Low Risk to Humans from Food Containing Melamine". USDA and U.S. Food and Drug Administration. May 7, 2007. Retrieved 2007-05-07; "Feds: Millions have eaten chickens fed tainted pet food". CNN. May 2, 2007. Retrieved 2007-05-02.*

20. Prior to Congress' passage of 21 U.S.C. § 2102, the Office of the Inspector General (OIG) had reported to it (as did the various FDA officials who testified before it) that the FDA's failure to formally enact proper rules and regulations had left it – and its officers, utterly impotent, unable to do more than "ask" for voluntary recalls by the makers of the tainted food.

21. Despite this – and contrary to law, all but twelve (12) years after a united Congress passed a specific law requiring the FDA to get its act together and conduct formal rulemaking relative to pet food *AND* animal feed, little has changed.

22. The FDA still has not conducted formal rulemaking, it is still relying upon disfavored (and nonbinding) desk policies to enforce a zero-tolerance, "Nonbinding" guidance policy.

23. To mask that it has yet to comply with federal law, the FDA has opted to engage several participating states (including, Colorado named herein) to enforce the disfavored, nonbinding desk policies on a zero-tolerance basis and as though they were bona-fide Rule.

24. The FDA's and participating states' noncompliance with federal law, while at the same time illegally enforcing the disfavored, nonbinding zero-tolerance guidance deprives the people of the freedom of food choice for their pets.

25. The FDA, AAFCO, and the participating states are arbitrarily and capriciously deciding what pet owners can and should feed their pets while disseminating misinformation harmful to Plaintiff's ANSWERS™ Pet Food brand and proprietary processes as though it were scientific fact.[18]

[18] Plaintiff's products plainly comply with the federal definition of "unadulterated" products as set forth within the Federal Food, Drug, and Cosmetics Act.

III. IDENTIFICATION OF PARTIES, JURISDICTION, AND VENUE

a. Parties

26. Plaintiff is a manufacturer of raw pet food based in Pennsylvania that distributes its products nationwide and – as is relevant herein, within the jurisdiction of this United States District Court, the District of Colorado.

27. FDA is a federal administrative agency that regulates the interstate distribution of all pet foods pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C 331(a).

28. AAFCO is a quasi-legislative enterprise created by local, state, federal, and international regulators to define and establish regulations for pet food and feed ingredients, in addition to setting standards for nutritional adequacy. Most states in the U.S. have adopted the Model Bill and Regulations established by AAFCO. While participation and membership in AAFCO is voluntary, if a state agency wishes to receive monies from the FDA, they must agree to enforce the FDA's policies and procedures in full.

29. The private sector must pay a fee to attend AAFCO meetings, pay fees for access to work products developed by AAFCO, and must be approved by the AAFCO Board to participate on Advisory Committees but — even if approved — the private sector is not allowed to vote on Advisory Committee business (the FDA and state governmental actors can only vote on such business).

30. Pursuant to 21 U.S.C. § 2102, *supra*, as adopted, AAFCO was intended by Congress to merely have a seat at the Regulatory Table but the FDA has instead delegated all mandated regulatory power concerning pet food to AAFCO as though it was the FDA itself.

31. AAFCO and its state government members, at the behest of the FDA, using FDA monies and directives, and as specifically relevant herein, acted in concert and/or coordination with the FDA to sample and debase Plaintiff's products within various states, specifically within the State of Colorado.

32. Per published information on AAFCO's website, "In the world of commercial animal feed, including pet food, three agencies work cooperatively to recognize the ingredients that are used to manufacture feed and the state laws that regulate commerce in animal feed and pet food among the 50 states. These three agencies are AAFCO, FDA, CVM[19], and your state government."[20]

33. Colorado's Department of Agriculture ("CDA") is an active participating member of AAFCO who – funded by the FDA, pulled Plaintiff's products from the shelves of one of its Colorado retail stores selling Plaintiff's products (ANSWERS™ Pet Food has not less than four (4) retail stores selling Plaintiff's products in Colorado Springs alone) – after what is believed will be proven the CDA's mishandling Plaintiff's products pursuant to the plain instructions thereupon and in noncompliance with the CDA's own laboratory Standard Operating Procedures (SOPs), tested them for "adulterants" as defined by AAFCO (a *definition* adopted by the CDA as

[19] Center for Veterinary Medicine (CVM), a branch of the FDA (and thus not individually named herein) that regulates the manufacture and distribution of food, food additives, and drugs that will be given to animals, monitors and establishes for animal feed contaminants, including those for pet food and is the division that issues assignments for the collection of product samples for testing, determination of whether a product is considered adulterated, provides informational updates, and assists in the coordination of recalls.

[20] AAFCO: The People Behind Animal Feed and Pet Food, ©2018 Association of American Feed Control Officials (AAFCO) 1800 S. Oak Street, Suite 100, Champaign, IL 61820-6974 http://www.aafco.org

its own), and declaring them "adulterated" because of the presence of a non-specified form of Salmonella.[21]

34. Kate Greenberg is the Commissioner of the Colorado Department of Agriculture, charged with administering her office lawfully and justly, and stands responsible for the adherence to all Orders of this Court.

35. Laurel Hamling is the Program Administrator of the Colorado Department of Agriculture's Feed Program, responsible for instituting and enforcing the FDA/AAFCO Guidance Policies in conjunction with AAFCO's other participating member states (and within Colorado), including the enforcement actions undertaken against Plaintiff outlined herein.

36. Scott Ziehr is the Regulatory Administrator of the Colorado Department of Agriculture's Feed Program, responsible for instituting and enforcing the FDA/AAFCO Guidance Policies in conjunction with AAFCO's other participating member states (and within Colorado), including the enforcement actions undertaken against Plaintiff outlined herein.

b. Jurisdiction

Plaintiff Asserts Subject Matter Jurisdiction Pursuant To
28 U.S.C. § 1331 and 28 U.S.C. § 1367.

37. Pursuant to the FD&C Act a food is adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall ***not*** be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health." 21 U.S.C. 342(a)(1) (emphasis added).

[21] The CDA is currently prosecuting Plaintiff in state proceedings as a result of their test results and Plaintiff is vigorously defending themselves from those allegations.

38. The "FDA considers a pet food to be adulterated under section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)) when it is contaminated with ***any*** Salmonella and will not subsequently undergo a commercial heat step or other commercial process that will kill the Salmonella." Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals ("zero tolerance policy") (emphasis added). The Compliance Policy Guide also states, "[y]ou can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations." Plaintiff uses both a science and time proven alternative approach through fermentation and Hurdle Technology and proprietary processes for protection of the products to a level that would not ordinarily render it injurious to health.

39. The FDA's Compliance Policy itself plainly states – and its local and state partners will plainly admit— that this zero-tolerance tolerance policy should be viewed only as a recommendation ("Contains Nonbinding Recommendations").

37. As was noted by Congress and the Office of Inspector General (OIG), the FDA's guidance documents, *including this guidance*, do not establish legally enforceable responsibilities, period.

38. The FDA itself instructs that the use of the word "should" in FDA guidance means that something is suggested or recommended, but not required.

39. Therefore, the FDA will argue this Compliance Policy Guide Sec. 690.800 is not a final agency action that conclusively determines that all pet food containing *Salmonella* is adulterated. It is a "recommendation" the FDA – through AAFCO, compels state regulatory agencies to enforce in exchange for a piece of roughly $11,100,000.00 in FDA funding.

40. Despite its "Nonbinding" nature, the Memorandums of Understanding between the FDA, AAFCO, and its several participating state regulatory agencies, requires that a zero-tolerance *Salmonella* standard be enforced as if it is a final agency action.[22]

41. For example, the CDA has adopted a definition of adulteration that creates a state-level zero-tolerance *designation* that mimics the FDA's zero-tolerance guidance. This state level action was made despite the fact that it is scientifically wrong and flies in the face of the Federal Food, Drug and Cosmetic Act's defined terms, as well as the language contained in the Colorado Commercial Feed Act. The mere presence of *Salmonella* does not mean the food is per se "adulterated" pursuant to the FD&C Act.[23]

42. Because of this statutory problem with zero tolerance, AAFCO carries the FDA's water with their Model Bill and Regulations language that they press the states to use.

43. AAFCO's Model Bill and Regulations provides the following: "A food shall be deemed to be adulterated . . . if it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . . " This is very different from the FD&C Act because it omits the restriction placed on considering food adulterated by naturally occurring substances.

44. Armed with their policy guidance and cooperating states that adopt AAFCO's very different definition of adulteration, the FDA attempts to compel Plaintiff to recall its

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[22] The regulatory members of AAFCO – including, as is relevant herein, Colorado's Department of Agriculture, employ the same bait and switch tactics in an effort to insulate themselves and AAFCO from associated enforcement liability between pet food and animal feed, as well as to enable preferential treatment to types of highly processed pet food and feed.

[23] There have been reported more than 2,500 different serotypes of *Salmonella*, many which are not pathogenic bacteria, just potentially pathogenic. Kristi McCallum, Microbiological Sciences and Feeds Unit Leader for the Colorado Department of Agriculture is on-record parroting the FDA's desk policy regarding *Salmonella*, stating incorrectly and misrepresenting that "ALL serotypes are pathogenic to humans - …". That is simply not true and indicative of why Congress unanimously told the FDA, not AAFCO or any state regulatory agency, to conduct formal Rulemaking.

products, to justify their public shaming of Plaintiff for allegedly distributing adulterated foods, and to conduct frequent punitive inspections of the Plaintiff's manufacturing and other operational facilities.

45. Therefore, pursuant to the Administrative Procedures Act ("APA"), the FDA's zero tolerance *Salmonella* guidance is a final agency action because legal consequences are flowing to the Plaintiff because of it. Lacking any administrative remedy or other type of statutorily created procedure, this court has subject matter jurisdiction pursuant to 5 U.S.C. 704.

c. Venue

46. Plaintiff has over ninety (90) retail stores selling their products in the State of Colorado, with not less than four (4) in the Colorado Springs area alone.

47. The FDA, through the CDA has chosen to prosecute Plaintiff for alleged violations of the zero-tolerance policy despite their ultra vires adoption of this definitional rule and in direct defiance of a unanimous and united Congress that instructed it to regulate pet food processing "by regulation." 21 U.S.C. 2102.

48. This court is a proper venue for this claim because the FDA's enforcement of its Compliance Policy Guide Sec. 690.800 through the CDA resulted in a Notice of Alleged Violation, Stop Distribution Order, and filing of Charges against the Plaintiff for a lot code of raw pet food in Colorado.

49. The court has personal jurisdiction over the parties because the Plaintiff knowingly avails itself of Colorado law when distributing its raw pet food products here. The FDA's enforcement action, made through the FDA's de facto agents AAFCO and the CDA, that

resulted in a Notice of Alleged Violation, Stop Distribution Order, and filing of Charges against the Plaintiff occurred within the District of Colorado.[24]

IV. PREDICATE FACTUAL ALLEGATIONS

a. *Nonbinding Guidance With Binding Consequences: The Unlawful End-Run Around the Administrative Procedures Act (APA)*

50. The APA provides a procedure for agencies to create rules that are enforceable as law through rulemaking.

51. In 2007, a united and unanimous Congress responded to a National crisis by specifically mandating that the FDA follow the APA and conduct formal rulemaking relative to pet food and animal feed. *See.* 21 U.S.C. § 2102.

52. But the FDA (and the other executive agencies, to be fair) instead have engineered a way to make rules that are labelled "Nonbinding" yet treated as the law of the land by abusing their ability to promulgate guidance and relying on an exception to formal rule-making contained in 5 U.S.C. 553(b)(3)(A). This (to be construed narrowly) exception involves "interpretative rules, general statements of policy, or rules of agency organization procedure, or practice."

53. Unlike real rules—made through formal rulemaking-- this type of guidance does not normally get the benefit of judicial review because the agencies argue that guidance policies are merely interpretative rules "that merely interprets a prior statute or regulation and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties." *National Mining Assn. v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014).

[24] CDA is plainly acting as the FDA's de-facto agent – through AAFCO and its participating member states, in targeting Plaintiff for inspections and prosecution. Moreover, Plaintiff is registered and licensed in Colorado – with over ninety (90) retail stores selling their products located within the State (four (4) alone in the Colorado Springs area) and submits all products and labeling for approval for sale within the state.

54. When the FDA says that all of their guidance is mere interpretation and does not impose any obligations or requirements on regulated entities, this is false (i.e., regulated entities are required to provide access to company documentation, enter data in the Reportable Food Registry, publish a recall, warning notices, etc.). All it really means is that the FDA followed no formal prerequisites to issuing that guidance.

55. Absolute power corrupts absolutely and, as the pet food and animal feed crisis of 2006-2007 revealed, the FDA's unchecked ability to promulgate guidance policy using the exception to formal rulemaking creates a significant risk.

56. Moreover, the FDA is flexing power in an undemocratic manner and against the spirit of the APA. Professor David Franklin observed that:

> Often these policy decisions in effect command compliance from regulated industries and thus have substantial practical effects on the public, regardless of whether they are framed as mere guidance's, interpretations, or tentative policy statements. It would seem inconsistent with both legislative intent and democratic theory to allow agencies to make such decisions without public input whenever they wish.

David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut.* 120 Yale L. J. 276, 305 (2010).

57. Professor Mark Siedenfeld remarked that this system "leaves much leeway for agencies to abuse guidance documents by depriving stakeholders of opportunities to participate in their development and of obtaining substantive judicial review of them." Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents.* 90 Texas L. Rev. 331, 331 (2011).[25]

[25] As Justice Scalia observed in his concurrence in *Perez v. Mortgage Bank Ass'n*, the deference that agencies receive under *Chevron*, *Seminole Rock*, and *Auer* means "[a]gencies may now use these rules not just to advise the public, but also to bind them." 135 S. Ct. 1199, 1212 (2015).

58. This type of end-run around formal rulemaking and the FDA not meeting the requirements, criteria and procedures of the Food, Drug and Cosmetic Act is unlawful when the guidance promulgated is treated like a law by the agency promulgating the guidance.

b. Plaintiff's Business

59. Plaintiff manufactures and distributes high quality raw pet food with a "farm to bowl" philosophy that, instead of using high heat, high pressure, or irradiation—all processes that denature proteins to control bacteria-- uses an alternative approach that satisfies the requirements of the applicable statutes and regulations through fermentation, Hurdle Technology, and other proprietary processes to control bacteria in its product. This includes inoculating the product with Lactic Acid Bacteria (LAB) to a level that potential pathogens such as *Salmonella* are either eliminated, reduced, and/or have their growth inhibited by this bacterial competition.

60. Plaintiff manufactures and distributes raw meat and poultry pet food through their own meat processing plant and, until just recently, a United States Department of Agriculture (U.S.D.A.) inspected and certified processing plant approved for processing meat for human consumption. Plaintiff also manufactures and distributes a number of other raw and fermented products such as raw goat's milk and raw goat's and cow's milk cheese treats, fermented raw cow's milk kefir, fermented fish stock, and turkey stock with fermented beet juice. These products are similarly regulated by the FDA.

61. Plaintiff's proprietary process is soundly based in verifiable science to either eliminate, inhibit the growth of, and/or reduce the presence of *Salmonella.* Just like the raw human food supply, the raw pet food supply will have microorganisms living on it at scientifically detectable levels that are not harmful to pets or humans in anyway whatsoever. Even dead cells of *Salmonella* can be detected on both human and pet food supply through

traditional testing and it is ludicrous to say that any amount dead *Salmonella* poses an infection risk.

62. However, understanding that *Salmonella* could be present, Plaintiff labels its products in a manner to alert consumers of the risk that the product may contain harmful bacteria: **"WARNING: NOT FOR HUMAN CONSUMPTION. THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA."** Plaintiff also provides Safe Handling Instructions.

63. In the case of *Salmonella*, whether or not it is an added substance is a scientific question that depends on the type of food.

64. For the foods that Plaintiff distributes, however, *Salmonella* is not an added substance because it naturally occurs in the products, just as it occurs in the same meat and poultry supply meant for human consumption.[26]

c. The Relevant Federal Law and Salmonella

65. The FDA's power to regulate the Plaintiff's business comes from two sources: (1) the FD&C Act and its charge to the Executive Branch to prohibit the distribution of adulterated food in interstate commerce, 21 U.S.C 331(a), and (2) the law at 21 U.S.C. 2102 and its charge to the FDA to create pet food processing standards "by regulation."

[26] It is illogical to label any amount of Salmonella an "adulterant" as it inherently cannot be such because it is naturally occurring and strains of such are ever present in us, our food, and our feed. *See, e.g.* 21 U.S.C. § 342(a)(1). This is why the United States Department of Agriculture (USDA) – the agency which regulates meat and poultry for human consumption, does not consider the mere presence of *Salmonella* an adulterated product and allows certain quantities using the same Food, Drug and Cosmetic Act law language and provision used by the FDA to regulate pet food. The FDA also allows *Salmonella* in animal feed, with the exception of approximately 8 certain serovars, associated with disease in the particular animal species consuming these feeds.

66. The term, adulterated, is defined by statute as a food that "bears or contains any poisonous or deleterious substance which may render it injurious to health; but in the case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health." 21 U.S.C. 342(a)(1).

67. Before the FDA can take administrative action pursuant to 21 U.S.C 331(a), it must first determine if the relevant substance is an added substance or is naturally occurring in the food.[27]

68. The mandatory "shall" means that the FDA has no power to prohibit the interstate distribution of Plaintiff's product unless it can prove that the food has an adulterant present, in this matter *Salmonella*, in sufficient quantities that would ordinarily cause injury to health.

69. If the FDA could prove that *Salmonella* in any quantity and of any serotype on pet food would ordinarily cause injury to health it could then promulgate a rule stating such and that would be enforceable, reviewable, and have clear legal consequences, but the FDA cannot prove such a position.

70. This is just one reason the United States Department of Agriculture (USDA) – the agency which regulates meat and poultry for human consumption, does not consider the mere presence of *Salmonella* to render food adulterated.

[27] Given the scientific fact that *Salmonella* commonly occurs in raw meat and poultry, the Plaintiff's raw pet food cannot be considered "adulterated" due to *Salmonella* so long as the *Salmonella* is of a quantity that "does not ordinarily render it injurious to health." *See, e.g.* 21 U.S.C. § 342(a)(1). There are over 2,500 serotypes of *Salmonella* and not all of them are pathogenic and injurious to health.

71. This is also why the FDA also allows detectible *Salmonella* in animal feed, with the exception of approximately 8 certain serovars that are associated with disease in the particular animal species consuming these feeds.

72. And Congress, in enacting 21 U.S.C. 2102, expressly told the FDA to promulgate such rules "by regulation" if *Salmonella* in any quantity and of any serotype on pet food would ordinarily cause injury to health.

73. The FDA, however, **cannot** prove the mere presence of *Salmonella* on pet food would ordinarily cause injury to health without quantifying and serotyping the *Salmonella* and therefore no such zero-tolerance rules should be promulgated without following these requirements set forth in the FD&C Act. .

74. But, as agencies are sometimes known to do, the FDA did not let a little thing like APA compliance temper its zeal for banishing *Salmonella* from pet food completely --and attempting to put the Plaintiff (and the whole category of raw natural pet food) out of business without any democratic or judicial check.

d. FDA's Compliance Guidance on Salmonella in Pet Food

75. The APA presumes that the agency will act to enforce the laws it is charged with enforcing through rule making.

76. The APA creates two main ways for an agency to propose and establish rules: formal hearings with claims supported by scientific evidence and the notice and comment proceeding. Rules created in this manner thereafter essentially carry the force of law and because these rules are so powerful, promulgating them requires extensive proof from the agency to justify the proposed rule.

77. In a November 2007 Report of the Subcommittee on Science and Technology entitles "FDA Science and Mission at Risk"[28], the FDA themselves highlighted three Major Findings: "1.2.1 The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak . . . 1.2.2 The FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability . . . 1.2.3. The FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate."

78. So, instead of going back to Congress to obtain funding for its Mandates, the FDA cheated. The FDA's solution lies in Compliance Policy Guides because it is easy and inexpensive to promulgate while difficult and expensive for the public to present meaningful competing science to challenge those guides. In sum, it allows for a means to an end that circumvents federal law, deprives persons, such as Plaintiff, their due process rights and their right to participate in the shaping of the regulations that govern them.

79. Despite the pitfalls of just issuing guidance, the FDA produces numerous compliance policy guides and consolidates them into a manual that is published and distributed nationwide. This manual covers a range of topics from the proper labeling for hollandaise sauce to the banning over-the-counter ear-drops that include a local anesthetic.

80. The forward from the manual makes it clear that the FDA relies on "Compliance Policy Guides [to] explain Food and Drug Administration (FDA) policy on regulatory issues related to FDA law or regulations [and] advise FDA's field inspection and compliance staffs, as well as the industry, as to the Agency's strategy and policies to be applied when determining industry compliance." Food and Drug Administration, Inspections, Compliance, Enforcement, and Criminal Investigations, *Foreword: Compliance Policy Guides (CPGs)*,

[28] FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology Prepared for FDA Science Board November 2007

https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm

81. While this gobbledygook is supposed to be the magic words that insulate this guidance from judicial review, by its own wording "determining industry compliance" indicates that the FDA uses this guidance to determine legal compliance by regulated industries with the FD&C Act. It creates a binding effect on the regulated industry and legal rights and responsibilities that flow from it, as described by Professors Franklin and Siedenfeld *supra*.

e. The FDA and AAFCO Member States are Properly Enjoined from Enforcing Compliance Policy Guide Sec. 690.800

82. At issue in this matter is Compliance Policy Guide Sec. 690.800, *Salmonella* In Food for Animals, issued by FDA in July 2013, and as enforced through AAFCO's participating member states.

83. Despite its bold header that labels its contents "Nonbinding," this guide clearly states that "FDA considers a pet food to be adulterated . . . when it is contaminated with Salmonella and will not subsequently undergo a commercial heat step or other commercial process that will kill the Salmonella."

84. Despite its bold header that labels its contents "Nonbinding," this guide further provides a three-step test for FDA to "consider" determining if pet food should be seized as adulterated due to *Salmonella*. That test requires (1) finding *Salmonella* in any quantity present in one subsample, (2) finding that the pet food will not be further processed by heat treatment or other method during manufacturing to eliminate *Salmonella*, and (3) the *Salmonella* is of any serotype.

85. While this is supposedly "Nonbinding" guidance that does not have the force of law, the FDA's use of this guidance gives it the force of law. The FDA transforms a Compliance

Policy Guide produced without procedural protections provided by the APA into the regulatory standard that is enforced in practice.

86. All one has to do to see that the FDA is actually using AAFCO and participating member states to apply a zero-tolerance *Salmonella* standard to raw pet food is to look at a list of recent voluntary raw pet food recalls due to *Salmonella* detected by FDA or a state counterpart. As is practice, the FDA compels manufacturers to issue voluntary recalls or face unspecified punitive action.

87. Similarly, the FDA issues documents "requests", not "demands" based on the application of the zero-tolerance *Salmonella* standard to pet food, but again if the manufacturer denies such a request, the FDA—through its regulating State agency—then threatens criminal and/or monetary punitive action. Plainly, as the Court has held, the threat of criminal and/or monetary punitive action can only come with final agency action. Thus, by any name, the FDA's guidance policies are – in fact, illegal shadow regulations properly subject to this Court's review.

88. The FDA is happier living in regulatory limbo (despite the National Pet Food and Animal Feed crisis of 2006/2007), when its Compliance Policy Guide is treated by most of the industry as the law of the land. Plaintiff is, frankly, an outlier. With extremely rare exception, everybody else "voluntarily" recalls after the FDA tells them to. This, combined with the relentless pressure placed by state regulators using the AAFCO definition that the FDA created, generally forces industry to their knees.

89. Herein, for example, the FDA enlisted the CDA to pull product from shelves to be tested by their state laboratory and slandered the Plaintiff's products. Despite this and on top of already punitive inspections, the FDA enlisted the other AAFCO member states to pull product

from shelves to be tested by their state laboratories and slandered the Plaintiff's products. For example, the state of Nebraska pulled products under what was reported as Collection Reason "STATE-FDA SURVEILLANCE", with a reported finding of *Salmonella* calling them adulterated, again slandering the Plaintiff's products. While the initial split sample sent by Nebraska Department of Agriculture (NDA) (supposedly of Plaintiff's product) confirmed the presence of *Salmonella*, there was insufficient quantity of material sent to Plaintiff to quantify and serotype the *Salmonella*. When additional quantity of the split sample was received and tested by an independent laboratory, four (4) consecutive tests could not detect any presence of *Salmonella.* Such consistent non-finding of the presence of *Salmonella* raises the concern of whether potential cross contamination could have occurred in the state's laboratory or other handling or transporting of the product. Regardless, as instructed by the FDA the state of Nebraska reported the Plaintiff's product on the national Reportable Food Registry because Plaintiff would not because of their position the Plaintiff's product was not adulterated nor did it ordinarily render it injurious to health . At the behest of the FDA, Nebraska took such actions without any known verification by the FDA, quantification of the *Salmonella*, completion of a Health Hazard Evaluation, and not meeting the other requirements of the FD&C Act. Nebraska also arranged to have Plaintiff's product pulled from retail store(s) and issued a Withdrawal from Sale Order.

90. On January 9, 2019 concerning the sampled product by Nebraska, the FDA issued a Public Warning Notice for A+ ANSWERS™ Straight Beef Formula for Dogs stating is was doing so because the product represents a serious threat to human and animal health and is adulterated under the Federal FD&C Act. The warning was made after the Plaintiff refused to conduct a voluntary recall of the product by the FDA. Within the public warning notice, the FDA

falsely states "Federal law requires all pet food to be free of pathogens, including *Salmonella.*" That is clearly the FDA applying the zero-tolerance rule substantively through intimation and public libel.

91. In this warning, the FDA recommended pet owners should throw the product away; clean refrigerators/freezers where the food was stored; clean and disinfect all bowls, utensils, food preparation surfaces, pet bedding, toys, floors, and any other surfaces that the food or pet may have had contact with; and clean up the pet's feces. The FDA also mislead the public in stating the Plaintiff recalled the product and even incorrectly identified the specific lot code of food being referenced. All these recommendations that libel the Plaintiff's goodwill and reputation is based on "Nonbinding" guidance that the FDA will maintain is unreviewable by this court.

92. It is reviewable though, and this court must enjoin the FDA's actions that have created an enforceable rule without following any of the procedural safeguards that are required for such may be created.

f. AAFCO'S Member States' Cooperation With the FDA is Illegal Lawmaking, Impermissible Shadow Regulation

93. On April 11, 2018, pursuant to an interagency agreement(s) between Colorado and the FDA and the FDA's call to the states for sampling of raw products, an inspector working for the Colorado Department of Agriculture collected a sample of raw pet food manufactured by the Plaintiff that was for sale at a pet store located in Littleton, CO.[29]

[29] This sample, what is believed to be noncompliant with proper handling procedures and noncompliant with Colorado laboratory standard operating procedures and Plaintiff's labeling.

94. Allegedly, the collected sample contained *Salmonella* and Listeria monocytogenes in an unspecified quantity.[30]

95. Colorado law, as with that of the several member states participating in AAFCO, provides a concurrent regulatory system for pet food where they enforce essentially the same statute the FDA enforces (the only difference between C.R.S. 35-60-107 and 21 U.S.C. 342(a)(1) is that the Colorado law uses the term "feed" instead of "food") but under the police powers of the State not the commerce clause powers of the Federal Government.

96. In contradiction to the Colorado Commercial Feed Act, however, Colorado defines "poisonous or deleterious substance" in an administrative rule, 8 CCR 1202-7, Part 13.1.1, as including any serotype of *Salmonella* in any detectible amounts.

97. Also like the FDA, Colorado has promulgated a zero-tolerance rule through the back door. Instead of conducting proper formal rulemaking, they simply adopted an FDA Compliance Policy Guide definition of what constitutes "adulteration" in pet food – *Salmonella* found in any detectable amount.

98. This decision was orchestrated and directed by the FDA and its agent AAFCO.

99. Moreover, the CDA failed to comply with Colorado's requirement that there be a scientific or technical evaluation of the rationale of the rule and other administrative rule making requirements and allowances before adopting the rule, as well as ignored the provision that no such regulation shall conflict with federal law.

[30] Plaintiff's independent third-party testing of the split sample detected *Salmonella* in a quantity that would not ordinarily render it injurious to health and just a generic nonpathogenic Listeria, not Listeria monocytogenes. Subsequent testing by Plaintiff after the split sample was time and temperature abused proved Plaintiff's fermentation and Hurdle Technology was working, greatly reducing the quantity of *Salmonella*, and eliminating the Listeria all together.

100. This rule also conflicts with the language of the Colorado Feed Law, §§ 35-60-107(1)(a) and (2)(a) C.R.S. These provisions state, in relevant part:

> No person may manufacturer or distribute in this state any feed that is adulterated or misbranded. . . .(2) A feed is adulterated if any of the following apply: (a) The feed bears or contains any poisonous or deleterious substance that may render the feed harmful to health; except that, if the poisonous or deleterious substance is not an added substance, a feed shall not be considered adulterated under this subsection (2) if the quantity of such substance in the feed does not ordinarily render it harmful to health.

C.R.S. 35-60-107. It contains the exact restriction Federal law contains on defining a food as adulterated.

101. And, the FDA – through AAFCO (and the millions it provides to participating member states), plainly confirms that the CDA will strictly enforce the FDA's zero-tolerance position —and on the FDA's terms —before they allocate a percentage of the $11,100,000.00 allocated to AAFCO's participating member states that agree to do its bidding.

102. The FDA's use of AAFCO's several participating member states to enforce its' zero-tolerance position corrupts the "laboratories of democracy" model our Federal Republic is based on. Instead of the Federal Government adopting successful state level regulations, the FDA is instructing state regulators to adopt Federal guidance as their own regulations – and doing so with a plain intent to evade the Constitutional disinfectant of this Court and, plainly, also around Congressional intent, the legislative process, and the APA. [31]

[31] It is also plain that the FDA and the enlisted AAFCO's several participating member states coordinated to try and bend Plaintiff. These member states took actions against Plaintiff and their products. In addition, besides the Colorado Department of Agriculture's actions against them, the Center for Veterinary Medicine (CVM) of the FDA continued to sample Plaintiff's products in the manufacturing facility and at the cold storage warehouse before being distributed, which places a burden on a small manufacturer to hold product, combined with taking months to report any test findings (if at all) even though the FDA is required to report findings in an expedited manner and when a finding occurs considers the finding (months later) an urgent matter to address by the manufacturer.

103. The CDA continues its prosecution of Plaintiff at the direction of the FDA for a matter involving a balance of less than 80 pounds of a specific lot code of product for sale in the whole state (after quantities were removed for sampling and testing), with contradictory test results between Plaintiff and prosecutor, with what is believed to be noncompliance with Colorado's laboratory Standard Operating Procedures regarding sampling, protecting, testing, and reporting of Plaintiff's sample, after the Plaintiff took steps to have the questioned product immediately stopped from distribution and pulled from retail stores, and with no reported illnesses.

104. Why so much effort given the facts? Because Plaintiff would not plead guilty, would not pay $750, would not accept the zero-tolerance administrative rule as law, and was unwilling to waive its right to challenge this rule, currently and in the future.

105. Colorado, bound to enforce the FDA's "Nonbinding" policies because it took monies specifically to do so, must promulgate and prosecute this zero-tolerance criterion.

106. All these actions, *in toto*, impose obligations upon the Plaintiff creating legal consequences on the Plaintiff that flow from the FDA's "Nonbinding" guidance that is really a rule and, in this instance, the FDA is using Colorado (like other AAFCO state members such as Nebraska, New Jersey, and Pennsylvania, all which took actions against Plaintiff starting the day after Plaintiff filed its response to Colorado's charges) as its pawn, an instrument to circumvent Congressional intent.

g. The FDA's Backdoor Regulations Violate The APA And, Thus, Are Unenforceable

107. The FDA's conclusion contained in Compliance Policy Guide Sec. 690.800, is a reviewable Final Agency Action because it imposes a legal obligation upon Plaintiff to ensure that their raw pet food has zero *Salmonella* presence, and legal consequences are currently flowing from that "guide."

108. This guidance is far more than a "mere interpretation" of the term "adulterated."

109. This guidance is a substantive rule which requires at least a formal notice and comment procedure.

110. While the FDA says this is not a substantive rule, it is treated by the FDA as a substantive rule-in-fact.

111. It is treated as a substantive rule when the FDA goes through the sham of "requesting" Plaintiff conduct a recall and then shaming Plaintiff publicly for violating a "Nonbinding" rule.

112. It is treated as a substantive rule when FDA sends its inspectors to Plaintiff's facilities to conduct relentless inspections based on alleged violations of state-level zero-tolerance rules.

113. It is treated as a substantive rule when the FDA decides to compel the CDA and NDA to enact a zero-tolerance rule that it is unwilling to enforce itself and instructs the CDA and NDA to target the Plaintiff with enforcement of it.

114. It is treated as a substantive rule when the FDA's Center for Veterinary Medicine issues an assignment to sample raw pet foods nationwide to detect the presence of *Salmonella*.

115. The FDA, in their actual enforcement of Compliance Policy Guide Sec. 690.800, *Salmonella* In Food for Animals, has adopted a substantive rule that requires pet food contain zero *Salmonella* to be considered non-adulterated.

116. This rule was adopted contrary to law.

117. In short, the FDA ignored Congress and federal law by simply turning a desk policy into a rule enforced through several AAFCO participating state regulatory members.

118. Because this rule was adopted in non-compliance with the APA and denies the Plaintiff due process, this court should ENJOIN the FDA from enforcing it in any manner, including cooperation with states to enforce this rule and stop issuing public warnings that are based on violations of this rule and ignoring constitutionally protected rights, and DECLARE that rule was adopted *ultra vires*.

h. Enforcement of FDA's Backdoor Regulations Violates Constitutional Separation of Powers

119. Article 1, Section 1 of the Federal Constitution vests all legislative power in the Congress of the United States.

120. If the FDA can prove all of the more than 2,500 types of *Salmonella* are pathogenic and harmful to humans, then the FDA should seek the Legislative Branch to pass a law amending the FD&C Act. The Executive Branch can only enforce law created and passed by the Legislative Branch.

121. The FDA is an Executive Branch agency that has only the powers granted to it by Congress that are non-delegable.

122. The Legislative Branch has instructed the Executive Branch to prohibit the distribution of adulterated food in interstate commerce, in accordance with the requirements, criteria and procedures contained in the FD&C Act.

123. Likewise, the Legislative Branch has instructed the Executive Branch to allow interstate distribution of products not meeting the definition of adulterated product if complying with all other legal requirements and not ordinarily rendering it injurious to health.

124. To constrain the Executive Branch's power to define the term "adulterated food," the Legislative Branch specifically excluded from the term any food that contains a potentially poisonous or deleterious substance that naturally occurs in the food so long as the quantity of the

potentially poisonous or deleterious substance is of such quantity to not ordinarily render it injurious to health. 21 U.S.C. 342(a)(1).

125. Through their zero-tolerance rule on *Salmonella*, the FDA is violating the separation of powers mandated by the Federal Constitution by creating rules disguised as guidance with the effect of laws. Such is a violation of the non-delegation doctrine.

126. Former Judge Gorsuch recited the essence of the non-delegation doctrine best, "[i]f the separation of powers means anything, it must mean that the prosecutor isn't allowed to define the crimes he gets to enforce." *United States v. Nichols*, 784 F.3d 666, 668 (10th Cir. 2015) (dissenting).

127. But that is exactly what the FDA is doing here, they are defining the crime of introducing adulterated food and then taking enforcement actions based on their definition. All the while, their definition does not comply with the special treatment non-introduced substances are afforded by statute.

128. While Congress has the power to delegate defining the term "adulterated," it must do so with at least an intelligible principle to temper the zeal of the FDA.

129. Given that the intelligible principle contained in the FD&C Act at 21 U.S.C. 342(a)(1) leads to a delegation of power by Congress to the FDA, that intelligible principle does not delegate to the FDA the power to declare ANY pet food with ANY trace of *Salmonella* of ANY serotype is adulterated.

130. With that said, Plaintiff shares Professor Sean Sullivan's opinion that "[o]f all constitutional puzzles, the nondelegation principle has long been one of the most perplexing." And because of the perplexing nature of the intelligible principle test, the Plaintiff complains that this is one of those rare cases worthy of setting aside *stare decisis* and creating a new test for the

non-delegation doctrine if this court finds that there is an intelligible principle that the FDA is following when it established and enforced a zero-tolerance rule for *Salmonella*.

V. SUMMATION OF CLAIMS

131. For clarity, Plaintiff is specifically levying the following claims:

a. The FDA created a rule *ultra vires* that provides that ANY pet food is adulterated when it contains ANY trace of *Salmonella* of ANY serotype because the FDA did not follow the proper procedure called for by the APA to promulgate rules, as well as did not follow the requirements and procedures contained within the FD&C Act. The fact that the FDA calls this rule "nonbinding guidance" is simply a sham given the totality of the circumstances that show this guidance carries the force of law. Because the rule was adopted *ultra vires* and imposes obligations on the Plaintiff who suffers legal consequences from it and continued irreputable harm, the Plaintiff is entitled to a declaration that the rule is illegal and an injunction preventing the FDA from promulgating that guidance or enforcing that rule.

b. The FDA is not following the intelligible principle Congress gives it when defining whether food is adulterated or not. That intelligible principle is contained specifically at 21 U.S.C. 342(a)(1) and specifically excludes from the FDA's regulatory power the ability to declare a food adulterated due to the presence of *Salmonella* if it is not an added substance and cannot be considered adulterated without quantifying the amount detected and identifying the serotype detected, without performing a Health Hazard Evaluation, without properly classifying a recall, and without following other criteria and procedures contained in the law. Because the FDA is not following the intelligible principle created by Congress when it defines ANY pet food as adulterated when it contains ANY trace of *Salmonella* of ANY serotype, the zero-tolerance rule is unconstitutional, and the Plaintiff is entitled to a declaration that the rule is unconstitutional and an injunction preventing the FDA from promulgating that guidance or enforcing that rule.

c. If the FDA is following an intelligible principle when it created the zero-tolerance standard, then the intelligible principle rule is worthy of constitutional reconsideration given that the intelligible principle test allows for excessive delegation of Congressional power, as demonstrated by the facts pleaded herein. Under a more stringent test, the FDA is not constitutionally delegated the power to declare ANY pet food adulterated when it contains ANY trace of *Salmonella* of ANY serotype. Because of this, the Plaintiff is entitled to a declaration that the rule is unconstitutional and an injunction preventing FDA from promulgating that guidance or enforcing that rule.

VI. CONCLUSION

132. Because the FDA is not delegated the power to establish a zero-tolerance rule for *Salmonella,* the enforcement of this rule through the sham of "guidance" should be ENJOINED

by the court with a DECLARATION that FDA has no power to enforce the zero-tolerance standard in any way.

WHEREFORE, Plaintiff prays this Honorable Court:

(1) Require all previous claims and references of Plaintiff distributing an adulterated product in which the FDA failed to conduct, follow, and comply with all the requirements, criteria and procedures of the Food, Drug and Cosmetic Act and resulting inspection reports, the Reportable Food Registry listing(s), and any other federal report or record initiated from pursuit of enforcement of the zero-tolerance Compliance Policy Guide be expunged from all federal and state records;

(2) GRANT Declaratory Judgment that Plaintiff was denied due process rights and FURTHER GRANT an injunction for the FDA and AAFCO's several participating member states to cease and desist from continued application and enforcement of Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals , as well as suspend any pending related enforcement actions specific to the application of this Compliance Policy Guide;

(3) PROHIBIT Defendants from reintroducing similar Compliance Policy Guides that do not strictly follow the Food, Drug and Cosmetic Act or attempt to circumvent the Administrative Procedures Act;

(4) PROHIBIT Defendants from creating artificial, false, and misleading appearances with respect to raw pet food products, safety, security, commodity, and currency (including removal of such from existing federal government websites and other means of publications); and/or

(5) Award Plaintiff such other and further relief as this Honorable Court deems necessary and proper.

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