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 ADMINISTRATOR FOR THE COLORADO DEPARTMENT OF AGRICULTURE	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendants.	:	

PLAINTIFF'S COMBINED MOTION AND MEMORANDUM FOR INJUNCTIVE RELIEF PURSUANT TO F.R.C.P. 65(a)(2)

Comes now the Plaintiff, -- having filed suit against the above Defendants before this Court[1], moving this Court seeking to RESTRAIN the above Defendants from enforcing their rules and/or guidance policies in that the presence of any amount of *Salmonella* in pet food renders that pet food adulterated in which such rules and/or guidance policies do not meet the requirements, criteria and procedures of the Food, Drug and Cosmetic Act (FD&C Act).

[1] Plaintiff's Complaint herein was filed contemporaneously with this Motion pursuant to FRCP 65(a)(2) and is incorporated herein as though set forth in complete detail.

TABLE OF CONTENTS

I. PREDICATE FACTS

1. Plaintiff is a raw pet food manufacturer (pet food processor for national distribution) and its business is regulated by the Food, Drug and Cosmetic Act (FD&C Act). The Food and Drug Administration (FDA) is the agency charged with enforcing the Act.

2. In 2007, in response to a nationwide crisis with melamine contaminated pet food, Congress passed a law specifically tasking the FDA with creating pet food processing regulations in consultation with the relevant stakeholders, like the Plaintiff. The Plaintiff, and the other stakeholders in the pet food industry, would be subject to those regulations created by the FDA.

3. The FDA, however, did not create pet food processing regulations as directed by Congress. Congress explicitly gave the FDA a deadline of 2009 to promulgate regulations concerning pet food processing and the FDA simply ignored it.

4. The FDA, instead of promulgating pet food processing regulations, adopted a policy of issuing supposedly "Nonbinding" guidance for pet food processors to follow. The specific guidance at issue is the FDA's Compliance Policy Guide (CPG) 690.800 that pet food containing any amount of any serotype of *Salmonella* is *per se* adulterated, in contradiction to the FD&C Act (refer to CPG 690.800 for specific language).

5. The FDA prefers issuing "Nonbinding" guidance as opposed to making rules because making rules requires strict compliance with the safeguards of the Administrative Procedures Act (APA) and, issuing "Nonbinding" guidance does not. However, as described in detail in the compliant, the FDA uses this "Nonbinding" guidance as a shadow regulation for the use of the coercive "voluntary" recall requests and issuances of public health warnings. Through the Association of American Feed Control Officials (AAFCO), the FDA promulgates Model Bill

and Regulations based on the FDA's recommendations and other agreed upon provisions contained in the Memorandum of Understanding (MOU) 225-07-7001, and through AAFCO's participating state members compels states to change their standard to zero-tolerance and to do its on-the-ground inspection.

6. The FDA has used all of these methods to enforce the zero-tolerance *Salmonella* standard articulated in the "Nonbinding" guidance against the Plaintiff, making this guidance the actual Final Agency Action when it comes to *Salmonella* standards and regulations and pet food processing.

7. The use of these methods by the FDA to impose its Final Agency Action on the Plaintiff causes severe irreparable injury to the Plaintiff. On multiple occasions, this entire shadow regulatory apparatus has been employed against the Plaintiff.

8. First, a state that has been compelled by the FDA and AAFCO to adopt a zero-tolerance *Salmonella* standard performs an inspection of a sample of the Plaintiff's pet food. If the inspection finds any evidence of *Salmonella* presence (without regard to quantity, without conducting a Health Hazard Evaluation, without identifying the serotype, or without considering even if the bacteria are alive) that is then reported to the FDA. The state typically orders a Notice of Alleged Violation and Stop Distribution Order against the Plaintiff (manufacturer/processor), requires notice to the Plaintiff's distributors and retail stores and solicits an admission of guilt and payment of fines by the Plaintiff. Many states also place notice on the federal Reportable Food Registry (RFR).

9. Second, the FDA contacts the Plaintiff (pet food manufacturer/processor) and instructs them to "voluntarily" and publicly recall nationally the particular lot/batch code product(s), and also requires the Plaintiff to file a report on the federal RFR. If the Plaintiff

refuses to voluntarily recall, then the FDA will issue a nationwide public health warning alerting the public that *Salmonella* was found in the Plaintiff's lot/batch code product(s), the FDA considers the batch adulterated and unsafe because of it and instructs consumers to 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 to ensure safety. In the FDA nationally issued warning letters, the FDA uses fear mongering language falsely alarming the public the product in question represents a serious human and animal health risk, and in some instances possibly death; without the FDA following the FD&C Act in quantifying the alleged pathogen; without conducting a Health Hazard Evaluation, without properly classifying the requested recall; without following other requirements outlined in the FD&C Act; and without providing the Plaintiff (manufacturer/processor) any comprehensive supporting scientific results. The FDA will also make the false claim that federal law requires all pet food to be free of pathogens, including *Salmonella,* which contradicts the actual federal language of the FD&C Act.

10. This public shaming by the FDA is just one cause of irreparable harm.

11. Every time the FDA publicly declares that the Plaintiff's pet food is adulterated and unsafe because the FDA has set a zero tolerance for *Salmonella* it injures the Plaintiff's brand and reputation as a safe raw pet food manufacturer/processor. Instead of following the process demanded by law, that the FDA consult with the relevant stakeholders through the regulatory process, the FDA unilaterally imposes a rule on the Plaintiff that will result in the destruction of the Plaintiff's business. This will happen because consumers will likely heed the FDA's warnings and not buy the pet food, or because the Plaintiff will be forced by the

"Nonbinding" guidance to apply a heat or pressure kill step to their process, which renders the resulting dog food not raw and negates the positive nutritional benefits and wholesomeness of a raw diet pet food.

12. The FD&C Act clearly states that naturally occurring *Salmonella* does not render food adulterated unless it is an additive substance or in quantity that ordinarily would render it injurious to health.

13. Other causes of irreparable harm to the Plaintiff includes filed reports against the Plaintiff on the Reportable Food Registry (RFR), warning letters that remain on federal websites and often placed in front view of customers when researching the manufacturer/processor online, inaccurate third party media news reports, and disparaging of reputation of the Plaintiff and their brand to Plaintiff's business associates such as banks, insurance underwriters, credit lenders, distributors, retail stores and the public end user, as well as the pet food industry in general.

II. STANDARD FOR RELIEF

14. Plaintiff must satisfy the four elements of the familiar preliminary injunction test.

i. a substantial likelihood of success on the merits,
ii. irreparable injury in the absence of the injunction,
iii. its threatened injury outweighs the harm to the opposing party under the injunction, and
iv. the injunction is not adverse to the public interest.

Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008).[2]

15. Once the Plaintiff satisfies these factors this court may use its equitable powers to enter a preliminary injunction to prevent the injury complained of by the moving party. *Id.*

16. This matter is Ripe for formal adjudication by the Court pursuant to F.R.C.P. 65(a)(2).

[2] Plaintiff incorporates herein its Complaint (Doc. 1) as though set forth in complete detail below.

III. ARGUMENT

17. Plaintiff is entitled to injunction because its claims satisfy the test in this Circuit articulated in *N.M. Dep't. of Game & Fish v. U.S. Dep't of the Interior*, 854 F.3d 1236, 1246 (10th Cir. 2017).

18. In this matter, enjoining the FDA from taking any action against the Plaintiff because either the FDA or its state regulator partners detects the presence of any amount of *Salmonella* in the Plaintiff's pet food without following all requirements of the FD&C Act, including but not limited to, quantification of the alleged adulterant and conducting the Health Hazard Evaluation, proper classification of a recall, and without meeting the other requirements outlined in the FD&C Act will prevent irreparable harm to the Plaintiff's reputation and brand.

a. Substantial Likelihood of Success on the Merits

19. First, the Plaintiff demonstrates a substantial likelihood of success on the merits because the FDA is in violation of the APA and 21 U.S.C. 2102 by engaging in impermissible shadow regulation to regulate pet food processing instead of creating actual rules to regulate pet food processing. So long as the court agrees that the Plaintiff has standing to bring this claim, there is a substantial likelihood of success on the merits because the FDA did not comply with the required rulemaking formality before taking Final Agency Action on *Salmonella* regulations for pet food, in addition to not following the requirements and procedures stated in federal law in the FD&C Act.

20. Second, the Plaintiff demonstrates a substantial likelihood of success on the merits because the FDA is not following the intelligible principle contained in the FD&C Act.

21. Third, the Plaintiff demonstrates a substantial likelihood of success on the merits because, to the extent the FDA is following an intelligible principle, the Supreme Court is likely to change the intelligible principle doctrine.

i. The Only Thing Nonbinding is the Label: The "Nonbinding" Guidance Policy is Final Agency Action

22. The mere labeling of the guidance as "Nonbinding" has no effect on whether or not that guidance is Final Agency Action reviewable under the APA. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). "If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document . . . then the agency's document is for all practical purposes binding." *Id*. at 1021. The relevant test has two elements:

i. Does the action mark the consummation of the agency's decision making process?
ii. Does the action determine the rights or obligations of the regulated or from which legal consequences will flow?

Id. at 1022 (citing *Bennett v. Spear,* 520 U.S. 154, 178 (1997)). If both elements are satisfied, then there is Final Agency Action.

23. On the first element, there is no reasonable argument that the FDA has not consummated the decision making process on *Salmonella* with its guidance. The FDA, both by itself and through AAFCO state regulatory members, has decided that there should be a nationwide zero-tolerance standard for *Salmonella* in pet food. If the FDA wants to argue this guidance is not the final consummation of their thinking on the matter, then it should advise the public about the dangers of Salmonella in pet food are merely based on a preliminary opinion, not be allowed to specifically reference Plaintiff's name, particular lot code of food, not be

allowed to instruct the public to throw away the product, not infer the likeliness of severe health injury or even possibly death, and not reference any matter or information that cannot be proven by science or not resulting from following the requirements of the FD&C Act.

24. A recent case against the FDA regarding their abuse of guidance to make substantive legal changes is also illuminating on this point. *See American Academy of Pediatrics v. Food and Drug Administration, No. 8:18-cv-00883-PWG (D. Md. May 15, 2019)*. In that case, a 2009 law directed the FDA to regulate tobacco products and directed manufacturers of tobacco products to obtain premarket authorization from the FDA before marketing new products. Id. at 7. New tobacco products marketed without that premarket authorization would be considered adulterated by statute. Id. at 8. The FDA proceeded to drag its heels on enforcement of the premarket authorization law and in 2017 published guidance saying that it was exercising its enforcement discretion to extend the period it would not enforce the law until 2022. *Id*. at 10. In response to a suit brought by outraged stakeholders like pediatricians demanding judicial review of this abdication, the FDA explicitly argued that those stakeholders lacked standing to challenge the 2017 guidance because it was merely an interpretive rule, not a substantive one, and therefore not Final Agency Action reviewable by the APA. Id. at 11-12.

25. The court held that the guidance was Final Agency Action. Whether or not such guidance is actually Final Agency Action depends on a "host of factors." *Id*. at 39. But most important of these factors are the following three:

i. whether the agency has taken a definitive legal position regarding its statutory authority;

ii. whether the case presents a purely legal question of statutory interpretation; and

iii. whether the action imposes an immediate and significant practical burden on the regulated entity.

Id. (*citing Philip Morris USA Inc. v. United States Food & Drug Administration*, 202 F. Supp. 3d 31, 46 (D.D.C. 2016) (internal punctuation omitted). In this case, the court found that the FDA took a definitive position because it asserted the authority to delay premarket review required by the law. *American Academy of Pediatrics*, at 40. The court found that the guidance "concern[ed] a legal question of statutory interpretation: can premarket review be postponed, permitting a product to be on the market prior to approval, and if so, for how long?" *Id*. And further found that, while the challenge guidance did not put a burden on the regulated entities, it put a burden on the stakeholder Plaintiffs sufficient to make the FDA's guidance Final Agency Action. *Id*.

26. Turning to the facts of the case at hand, the *Salmonella* guidance represents a definitive legal position regarding the FDA's authority to enforce the FD&C Act by finding any pet food containing *Salmonella* adulterated. This is just like their guidance in *American Academy of Pediatrics* regarding the FDA's authority to enforce the Tobacco Control Act by exercising discretion to not enforce it.

27. Second, the *Salmonella* guidance concerns a legal question of statutory interpretation, can any amount of naturally occurring *Salmonella* render pet food adulterated when the statute requires proof that the quantity of *Salmonella* would ordinarily render the pet food injurious to health, as well as requires a Health Hazard Evaluation be performed? Again, just like *American Academy of Pediatrics* where the FDA was determining questions of law.

28. Third, the *Salmonella* guidance burdens the Plaintiff directly because of how the FDA engages this type of shadow regulation. The result of this "Nonbinding" policy are public health warnings issued by the FDA telling consumers that the Plaintiff's pet food is adulterated and dangerous and a state-level prosecution directed by the FDA, as well as threatened punitive actions including monetary penalties and/or criminal charges. The FDA also falsely notifies the

public that the Plaintiff is violating federal law in stating "Federal law requires all pet food to be free of pathogens, including *Salmonella*." That creates a concrete burden on the Plaintiff to either comply and sacrifice their raw product at the altar of pasteurization or face enforcement action. As evidence, the warning notice states "Without an effective control, such as cooking, raw pet food is more likely than other types of pet food to contain pathogens such as *Salmonella.* Pet owners who choose to feed raw pet food should be aware of the risks associated with these products.*"*

29. Now, it is unquestionable the precedent relied on in this motion relies on nonbinding interpretations of the law. However, their conclusions are validated by the very recently decided *Azar v. Allina Heath Systems*, 587 U.S. _____ (2019). While this case deals with a different judicial review statute than the APA, the Court's reasoning in this case demonstrates the Court's intolerance for agencies trying to avoid judicial review by mischaracterizing the substantive nature of their guidance.

30. *Azar* is about how the Department of Health and Human Services calculated a fraction that determined how much the government would pay a hospital serving a disproportionate number of low-income patients. *Id.* at pg. 3. The fraction is calculated pursuant to statute with the denominator being the time the hospital spent caring for patients who were "entitled to benefits under" Medicare Part A and the numerator being the time the hospital spent caring for Part A entitled patients who were also entitled to income support payments under the Social Security Act. *Id. "*The bigger the fraction, the bigger the payment." *Id*.

31. This was a simple calculation prior to 1997 when Congress created Medicare Part C where Congress allows beneficiaries elect to have the government pay their private health insurance premiums rather than paying hospitals directly for care. *Id*. This created confusion as

to whether or not patients who elected to participate in Part C should be counted in the fraction's denominator as "entitled to benefits" under Part A. *Id*. Counting these patients reduces the fraction's size and results in lower payments to the hospitals. *Id*. at p. 4.

32. The agency that administers Medicare has changed its position on this issue, initially interpreting the law to not count Part C patients and then electing to count Part C patients in 2004. *Id*. The 2004 interpretation was vacated by operation of a court order, but the agency still acted as if that interpretation was the law of the land when, in 2014, it published a spreadsheet announcing the fractions for the hospital that included Part C patients for the year 2012 using a policy adopted in 2014. *Id.* at pg. 4-5. Numerous hospitals injured by the reduced payments for 2012 brought suit against the government claiming that the agency adopted a rule without complying with the requirement of notice and comment. *Id*.

33. The Court held that the policy announced equated to a change in the "substantive legal standard" because it affected the right of a hospital to payment and therefore notice and comment was necessary. *Id.* at pg. 6. The analysis of this question by Justice Gorsuch is very short because it is clear that the change in the amount of money paid is a substantive part of the law, not merely procedural. *Id*. While Justice Breyer's dissent goes through a list of eight of agency actions that were held to be procedural even though they involved the payment of money, the fact that Justice Gorsuch's opinion dismisses those holdings without analysis demonstrates that time's up for agencies avoiding notice and comment by packaging up their substantive rules as guidance. *See id.* at 10-12. So, while *Azar* involved the interpretation of a non-APA judicial review statute that had its own unique phrasing (the opinion specifically disclaims the applicability of the APA's tests to the case because of its unique phrasing), the fact remains that

this case ratifies the notion that the substantive/procedural divide turns on the effects of the rule on the burdened parties, not on the labelling of the rule.

ii. Misleading the Public Through the Federal Register Does Not Count as Notice and Comment

34. Given that the *Salmonella* guidance is actually a substantive rule subject to judicial review, we turn to whether or not the FDA complied with the APA when creating that rule. The FDA did not comply with the APA because it mislabeled the guidance as nonbinding in the Federal Register, therefore frustrating the purpose of the notice and comment procedure by duping the public about the nature of the guidance. The fact that the FDA published this guidance for notice and comment is immaterial because of this.

35. The APA generally requires notice from the agency of any proposed substantive rule the agency wishes to make. 5 U.S.C. 553. Interpretive rules and general statements of policy are not required to pass through notice and comment unless another statute requires it. *Id.* "The object, in short, is one of fair notice." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 127 S. Ct. 2339, 2351 (2007).

36. Simply put, when an agency seeks notice and comment for an allegedly non-binding guidance policy and then turns around uses that policy as a binding shadow regulation there is no fair notice. Fair notice does not contemplate the agency misleading the public about the agency's intended use of something published in the Federal Register. That goes directly whether or not the agency's notice would "fairly apprise interested persons of the subjects and issues [of the rulemaking]." *Nat'l Black Media Coalition v. FCC*, 791 F.2d 1016, 1022 (2d. Cir. 1986) (internal citations and punctuation omitted). The FDA cannot get around the requirement of notice and comment on a substantive legal change by simply saying they had a notice and comment period for the guidance when the description of the guidance as "Nonbinding" is

illusory, and the guidance is actually treated as binding. An executive agency cannot get away with duping the public about the nature of something published in the Federal Register and then rely on that defective notice and comment procedure to shelter their rule.

37. Because the FDA treats the *Salmonella* guidance as a rule and imposes obligations upon the Plaintiff with legal consequences flowing to the Plaintiff because of this, and because the FDA mislead the public about the substantive legal changes their enforcement of the guidance causes, the FDA adoption and enforcement of the zero tolerance *Salmonella* rule is *ultra vires*.

iii. The FDA Is Not Following the Intelligible Principle Contained in the FD&C Act

38. The intelligible principle test requires the court to consider "whether Congress has supplied an intelligible principle to guide the [agency's] use of discretion." *Gundy v. Untied States,* 558 U.S. ___ (2019). This requires the court to "construe the challenged statute to figure out what task it delegates and what instructions it provides." *Id*. "Only after a court has determined a challenged statute's meaning can it decide whether the law sufficiently guides executive discretion to accord with Article I." *Id*.

39. The intelligible principle for *Salmonella* regulations for pet food for the FDA flows from 21 U.S.C. 2102 and 21 U.S.C. 342(a)(1). What we can glean from those statutes is that (1) the FDA is to establish pet food processing regulations and (2) naturally occurring adulterants are to be regulated in pet food to the extent that they exist in a quantity that "ordinarily render[s] it injurious to health."

40. The FDA's zero-tolerance rule on *Salmonella* pet food does not logically flow from this intelligible principle and usurps Legislative power. The law is not ambiguous and does not provide for agency discretion when it comes to the requirement of quantification. When the

FDA simply sets the quantification at zero for *Salmonella* in pet food it is not honoring that intelligible principle that Congress gives when exercising its discretionary power.

41. While the FDA will argue that setting the quantification at zero is fully within their discretion, that ignores the structure of 21 U.S.C. 342(a)(1) and the two classes of adulteration it creates: one for added substances (that does not require quantification) and one for non-added substances (that requires quantification). This creation of two classes that are separated by the requirement of quantification requires by implication that non-added substances do not render pet food adulterated unless there is a specific non-zero quantity that the FDA could set. Simply setting the bar at zero violates the intelligible principle of the statute that requires quantification, not zero-tolerance.

iv. The Supreme Court is Ready to Throw Out the Intelligible Principle Doctrine

42. Even if the FDA is following an intelligible principle contained in the FD&C Act, the Supreme Court has signaled the end of that doctrine in the recently decided *Gundy v. Untied States,* 558 U.S. ___ (2019). While the Court upheld the challenged statute against a non-delegation doctrine challenge, it did so in a curious way that signals that the reinvigoration of the doctrine and the death of the intelligible principle doctrine.

43. *Gundy* dealt with a challenge to the constitutionality of the federal Sex Offender Registration Act ("SORNA"). 34 U.S.C. 20913. SORNA gives the Attorney General the power to determine the applicability of SORNA's requirements to sex offenders who were convicted before the Act's passage. *Id*. A four-member plurality of the Court found no non-delegation doctrine problem because SORNA provided an intelligible principle; that the Attorney General was to "apply SORNA to pre-Act offenders as feasible." The actual holding of *Gundy* is not

what is remarkable about this case, it is the fact that it appears that the five justices who did not join the plurality opinion are ready to get rid of the intelligible principle doctrine.

44. The reason why the intelligible principle doctrine looks on its way out despite the upholding of SORNA is because *Gundy* was not in front of the full court, Justice Kavanaugh did not consider the case because he had yet to take the bench when argument was completed. This left the court without a clear majority to take on the intelligible principle doctrine and Justice Alito concurred with the plurality only because he felt it "freakish" to single out SORNA when a majority of the court was unwilling to consider the intelligible principle test. *See id*. (J. Alito concurring). In his concurrence Justice Alito specifically says that he is ready to reconsider this doctrine at the appropriate time. *See id*. Presumably this is when a full panel of nine justices can consider the issue.

45. Justice Gorsuch, and the two justices joining his dissent, did not share Justice Alito's timing concerns. In his dissent, Justice Gorsuch provides a compelling discussion on how the intelligible principle doctrine has been abused by the administrative state and that the judicial branch has been complicit in allowing an unconstitutional unification of power into the Executive branch.

46. But even if Justice Alito would join Justice Gorsuch's analysis is there was full panel, what of Justice Kavanaugh's likely tie-breaking portion? The Plaintiff's belief that, given the essentially 4-4 split, there is significant likelihood that the Court will reconsider the applicability of the intelligible principle test. If the court finds that intelligible principle test is in danger, supplemental briefing is suggested given the tricky nature of *stare decisis*.

b. Significant Risk of Irreparable Injury

47. The injury suffered by Plaintiff is irreparable. Although irreparable harm "does not readily lend itself to definition, "a plaintiff must demonstrate a significant risk that he or she will experience harm that cannot be compensated after the fact by money damages." 854 F.3d at 1250 (internal citations and quotations marks omitted). "That harm must be both certain and great, and not merely serious or substantial." *Id*. (internal citations omitted). Purely speculative harm does not suffice but showing significant risk of irreparable harm demonstrates the harm alleged is not speculative. *Id*.

48. In this matter, the risk of irreparable harm is manifest.

49. The impact on the Plaintiff's reputation from statements from that FDA classifying Plaintiff's products as adulterated cannot be remedied by monetary damages – it is a decade of work that cannot be replicated. [3]

i. Raw Milk Impact

50. For example, sixteen family goat farms and two Jersey cow farms that have been secured independently to supply all the raw milk for ANSWERS™ Pet Food would be forced to dump their milk or find another outlet for their milk. Specific standards and specifications on how the goats are raised, housed and fed were developed by ANSWERS™ owners over the life of the company (over 10 years) in conjunction with these farms. If these farmers were forced to suspend their milking operations, they would be forced to seek income from other sources

[3] See, *Digital Ally, Inc. v. Corum,* 042817 KSDC - No. 17-cv-02026-DDC-GLR (D. Kansas, April 28, 2017)(Finding loss of competitive market position to be irreparable harm because a "plaintiff may establish irreparable harm by "such factors as the difficulty in calculating damages, the loss of a unique product, and existence of intangible harms such as loss of goodwill or competitive market position."), *citing, Dominion Video Satellite v. Echostar Satellite Corp.*, 356 F.3d 1256, 1264 (10th Cir. 2004); *Hill's Pet Nutrition, Inc. v. Nutro Prod., Inc.,* 258 F.Supp.2d 1197, 1205 (D. Kan. 2003) ("[L]oss of customers, loss of goodwill, and threats to a business' viability can constitute irreparable harm."

(wherever possible), suspending their milk operations. It would take years to restart these operations, if possible at all, assuming these farms would still be available and operating.

51. Goat milk supply is very seasonally dependent because of when the majority of goats freshen (lactate). The majority of raw goat milk is supplied during the 2nd and 3rd quarter of the calendar year with steady drop off to very little by the end of the calendar year (4th quarter) going into the early half of the 1st quarter when the supply starts to increase the second half of the 1st quarter. Therefore, at a minimum if just a mere interruption occurred, it could take 6 months or longer to get even a fraction of the quantity of raw goat milk needed for the volume of products manufactured by Lystn -- and that assumes the specific inspected and approved goat milk and cow milk farm suppliers would still be operating and available.

ii. Discontinuance of Raw Goat Milk Cheese used to Produce Specific Raw Whey, a Key Ingredient for the Inoculation of Lactic Acid Bacteria (LAB)

52. The raw goat milk supplied to ANSWERS™ Pet Food is also utilized to produce their raw cheese treats. The specific raw whey that is utilized in these treats is a key ingredient necessary for the inoculation of lactic acid bacteria which provides competitive inhibition, a critical control step that ensures the safety and effectiveness of ANSWERS™ meat and poultry formulas for dogs and cats. Again, the cheese making process that supplies the raw whey is dependent on the consistent supply of ANSWERS™ raw goat milk and is not something that can just be suspended and then restarted. Lystn's raw goat milk whey is the subject of an ongoing research and development verification and testing program to be used in a patent filing – it is the result of a decade of work.

iii. Collapse of Integrated System & Supply Chain of Important Ingredients/Starter Cultures

53. The starter cultures developed specifically by ANSWERS™ Pet Food fermented products were developed and perfected over several years. Maintaining consistent operations is imperative to keep these important ingredients available and ready for production. Extended interruption to production would collapse the integrated system and supply chain that ANSWERS™ has built over the years with their local farmers, causing irreparable damage.

iv. Fermentation

54. Lystn's fermentation, very much like making wine, is an art that depends upon generations of experience. Lystn currently employs five Amish fermenters who ferment cow milk, goat milk, green tea, vegetables and sardines for Lystn products and processing. ***They must nurture the live cultures that have taken years to develop, keeping them alive and healthy.*** This process is time and environment sensitive in order to get the formulation and resulting product to comply with Lystn's specifications, such as proper pH level, while balancing it against palatability. Any discontinuance of operations would – at a minimum, mean replicating the cultures developed over the last 10 years which would be impossible in any timely manner to meet Plaintiff's immediate production demands.

v. Raw Material Sourcing

55. Over the past decade, Lystn has hand selected suppliers who agree to produce their products according to Lystn's specific standards. Lystn inspects its suppliers on-site to ensure the raw materials meet Lystn's strict quality specifications and philosophical requirements (GAP Rated, humanely handled livestock, no antibiotics, no hormones, organic, pasture raised, Non-GMO, etc.). These difficult to find raw material quality sourcing suppliers and the quantity available for Lystn's production volume is sporadic, cost and time sensitive, and

sometimes must be purchased months ahead of intended manufacturing date. Interruption of supply chain and such procurement efforts could set-back production of some products by many months.

vi. Livestock Farms

56. Lystn has set-up and made arrangements for local farmers to raise livestock exclusively for ANSWERS™ Pet Food. In the event of a shutdown, these family farms would lose substantial investment and livelihoods. Lystn would lose close to a year of livestock sourcing, as well as a monetary investment.

vii. Produce Farms

57. Lystn has 2 produce farms that grow over 150,000 pounds of produce per year exclusively for Lystn's meat formulas. The farmers have been developing these specific vegetables for many years. These vegetables are then fermented on the farms. If there was any disruption of Lystn, LLC manufacturing, these produce farmers would need to find an outlet for their produce. When restarting the manufacturing it would be impossible to source the same type and quality of vegetables required for Plaintiff's formulas to meet immediate production demands.

viii. Skilled Labor

58. Lystn LLC employs 12 manufacturing staff. For more than a year, this staff has been specifically trained to manufacture Plaintiff's unique processing developed exclusively by Lystn. If there was any interruption of manufacturing the staff would be forced to find other means of income and it could take a year and longer for Lystn to develop and train another fully staffed team to manufacture.

ix. Amish Relationship

59. Most of Lystn's manufacturing employees and farmers are of the Amish community. Much of Lystn's success is due to the unique abilities and talents of the Amish. Relationship and trust with the Amish community takes years to develop. If there was any disruption in the manufacturing and sales of Lystn's products, Lystn would lose the relationship and trust of Plaintiff's Amish partners because their current livelihood depended on by their families would be lost.

60. The destruction of the Plaintiff's business model due to the zero-tolerance rule is irreparable because the Plaintiff's proprietary process and trade secrets involve a complex system of vendors and growing standards, formulation components, and processes (as outlined above) that simply cannot be resurrected while Plaintiff litigates whether or not the FDA's zero-tolerance rule is legal. There is no injury more irreparable than death, and that is what the Plaintiff faces give the zero-tolerance standard that regulates their process out of existence. *See Schiavo v. Schiavo*, 403 F. 3d 1223, 1241 (11th Cir. 2005) (Judge Whittemore dissenting).[4]

x. Additional Reputational Harm

61. The FDA's shadow regulation will not only ruin Plaintiff's suppliers and supply chain, it will prevent the Plaintiff from using its trade secrets to manufacture the raw pet food it processes because the shadow regulation eliminates truly raw pet food from the market, causing the destruction of the Plaintiff's business. As a side note, the Plaintiff is currently preparing to file for patent ownership regarding its proprietary process and trade secrets which the U.S.D.A.

[4] While this matter does not concern the death of a person, the death of the bacteria cultures qualifies as irreparable injury just the same because the finality of death creates the irreparability, not what is dying.

has shown interest in such process for application in human food, and such false publications interfere with such advancements.

62. The reputational impact caused by the FDA's public statements that the Plaintiff's products are adulterated, in and of themselves create irreparable injury.[5] While this Circuit strictly requires satisfaction of the four-part test to obtain a preliminary injunction in any matter, prior case law explaining the reasoning for mandatory injunctions in trademark illustrates that reputational harm, like the harm suffered by the Plaintiff, is irreparable injury because loss of business goodwill and reputation has been found to be irreparable injury in post-*eBay* cases.

63. When the Supreme Court held in *eBay v. MercExchange, LLC* that patent infringement, by itself, does not mean the irreparable injury prong is automatically satisfied, it did not overrule the decades of precedent in intellectual property law that infringement, specifically of trademark, which causes damage to business goodwill or reputation, is irreparable. *See* 547 U.S. 388 (2006).

64. A recent case in this District makes it clear that *eBay* dispensed with automatic injections unless a statute provides for it, *but* that the loss of goodwill is still irreparable. *Underwood v. Bank of America Corp.,* No. 18-cv-02329-PAB-MEH (D. Colo. Dec. 19, 2018). In *Underwood*, the court found that sister circuit precedent applying *eBay* to all inductive relief cases was persuasive while still acknowledging that injury to goodwill, defined as "an intangible asset that denotes the business value of a company's brand and reputation," still merits injunctive relief because loss of reputation is irreparable. *See id. (citing Western Diversified Servs., Inc. v.*

[5] At Hearing, Lystn will present to the Court significant evidence of the FDA's slanderous and libelous conduct against it – from Google Search results to nationally distributed Warning Letters should the FDA challenge the assertion that it has so acted.

Hyundai Motor America, Inc., 427 F.3d 1269, 1274-75 (10th Cir. 2005); *Marks Org., Inc. v. Joles,* 784 F. Supp. 2d 322, 335 (S.D.N.Y. 2011)).

65. The harm in a trademark infringement case and this matter is the same, injury to goodwill and reputation because of consumer confusion about the quality of the product. If anything, *eBay* holds that the test must be uniformly applied without special rules for certain types of cases and upholding that injury to goodwill is irreparable is serves the purpose of *eBay*.

66. When a government regulator like the FDA speaks, the entire point is to call consumers to action. In this case, the FDA is explicitly calling the Plaintiff's products unsafe and telling consumers to throw it away and take sanitizing action. Such public pronouncements by a government regulator create a presumption that consumers are acting in response to it. Plaintiff need not present extensive economic testimony to prove lost sales when the FDA commits slander *per se* by falsely calling Plaintiff's pet food dangerous and adulterated. The obvious loss of reputation based on the FDA's illegal enforcement of the zero-tolerance *Salmonella* standard is – like the loss of vendors and a decade old processes and relationships, irreparable injury. As an example, Lystn has a chain of stores in the south and southeast that refuses to sell Lystn's raw chicken poultry products because of the FDA's false and misleading statements in a nationally distributed Warning Letter, and compounding the defamation of Lystn's product is the fact that the retail stores themselves notify customers of the FDA statements as the reasoningthe stores will not stock and sell the ANSWERS™ raw poultry chicken products.

c. The Balance of Harms Fall in the Plaintiff's Favor

67. Third, the threatened injury outweighs the harm to the opposing party under the injunction. The FDA suffers no harm if the injunction is granted because they are still allowed to go through the rulemaking process (as Congress directed them to) in order to fulfill their charge

of regulating the processing of pet food. This is balanced against the great harm Plaintiff suffers from the comply or die nature of this guidance.

d. The Injunction Does Not Harm the Public Interest

68. Fourth, the injunction is not harmful to the public interest. In this matter, an injunction serves the public interest ensuring, at least for pet food companies and their customers, that FDA does not brand products as adulterated due to *Salmonella* without first conducting rule- making to determine what quantities and serotypes of *Salmonella* would "ordinarily render [pet food] injurious to health" 21 U.S.C. 342(a)(1).

69. While the FDA will argue that constraining them from issuing public health warnings about the detection of *Salmonella* in the Plaintiff's pet food contravenes the public interest by preventing consumers from knowing that the Plaintiff's pet food may be dangerous, this argument is not persuasive because (1) the FDA's conclusions about the dangers of *Salmonella* are not founded in science (if they were then the FDA could just make a rule) and (2) the product that Plaintiff sells is clearly labelled as potentially containing *harmful bacteria and is transparent to the consumer about the risks*. Plaintiff's labels states: "WARNING: NOT FOR HUAMN CONSUMPTION. THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA." The Plaintiff's label also provides safe handling instructions. Essentially, the FDA's argument is that the public interest is served by their ability to publicly pronounce Plaintiff's pet food as adulterated and unsafe despite the fact there is no evidence that the pet food is actually adulterated pursuant to the statute. In the event Plaintiff's product is sampled and tested and found to possibly contain *Salmonella,* the FDA still has a course of action by simply following the requirements and procedures contained in the FD&C ACT.

IV. CONCLUSION

70. Congress makes the laws, the courts interpret the laws, and the executive branch enforces the laws; this separation of powers is central to our rule of law. And *Azar* shows us agencies do not have free reign to make substantive legal changes with unreviewable guidance.

WHEREFORE, Plaintiff prays this Honorable Court:

(1) Require all previous and future 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 Animal Feed, 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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