(Sent 4/5/2016 via. E-mail with hardcopy to follow in the mail or overnight delivery)

April 5, 2016

Robin M. Rivers
Compliance Officer
U.S. Food and Drug Administration
U.S. Customhouse, Room 900
2nd & Chestnut Street
Philadelphia, PA 19106

Anne E. Johnson
Acting District Director-Philadelphia District Office
U.S. Food and Drug Administration
U.S. Customhouse, Room 900
2nd & Chestnut Street
Philadelphia, PA 19106

Re: Response to March 17, 2016 WARNING LETTER sent to Lystn, LLC

Dear Ms. Rivers and Ms. Johnson:

This letter is to acknowledge receipt and respond to the March 17, 2016 WARNING LETTER sent to Mr. Keith A. Hill, President of Lystn, LLC. It is extremely perplexing to not only receive such correspondence from the Food and Drug Administration 117 days after our last communication to the FDA, but a communication that is now introducing new alleged violations with inaccurate information for which we have not previously received any written notification. The FDA in making inaccurate claims against our product and operations is putting at risk Lystn's company brand and products and our very existence, all after multiple attempts by Lystn to establish open communication and a working relationship, as well as Lystn's willingness to make concessions on points we disagree with in the interest of appeasing the FDA.

In an effort to be clearly compliant and responsible in our obligation to respond to the WARNING LETTER, our response will first briefly summarize the inaccuracies and/or contradictory claims contained in the WARNING LETTER followed by addressing each paragraph in further detail including corrective actions. Under separate cover in a supplementary letter with this same date, Lystn shares with the FDA our ongoing frustration, complaint and position as to how the FDA has handled the investigation into Lystn's products and operations.

SUMMARY OF INACCURACIES and/or CONTRADICTORY CLAIMS CONTAINED IN WARNING LETTER

- ***Lystn never received any results and is not aware of any testing on October 5, 2015*** as claimed by the FDA. Hard copy test results that were sent to Lystn by the FDA dated 10/8/15 reference speciation of Salmonella Poly B, we are confident this is not results from one of our samples as we have no hard copy test results from the FDA of a positive for Salmonella prior to 10/8/15.

- ***The FDA continues to claim Lystn's products are adulterated even though the FDA is fully aware of our comprehensive steps taken with extensive testing by an independent accredited laboratory proving our product fits into the exemption of not being considered Adulterated. The non-action by the FDA over the past 7 months confirms the FDA never believed our products presented a health risk to warrant a forced recall.***

- While Lystn has communicated to the FDA in correspondence that we incorporate additional safety measures in our products recognized by science as proven and safe since science came into existence (fermentation), and qualitative testing some of our ingredients showing protection of our food from bad bacteria, ***contrary to the FDA's claim there is nowhere on our website where we make the claim it controls "harmful bacteria".***

- Since the FDA could not justify adulteration of Lystn's product from the mere presence of Salmonella because of

no proof presenting a health risk, and after the FDA could not validate adulteration of our food from the claim of being manufactured in unsanitary conditions because of being manufactured in a USDA inspected and approved plant, ***the FDA now claims Lystn's Chicken Formula dog food products are adulterated because of misbranding of food additives within the meaning of Section 409(a)(2) of the Act [21 U.S.C. § 348(a)(2)]. While the FDA is trying to raise question on known healthy ingredients used by a small up and coming raw pet food company such as Lystn to protect pet food and the public, the FDA looks the other way on large pet food companies (represented by powerful trade associations) with significant egregious misbranding*** by having millions of tons of pet food on the market claiming use of "meat and bone meal", "soybean meal", "chicken-by-product meal" and much more. ***In addition, the FDA and State Departments of Agriculture overlook serious violations of law such as non-slaughtered/4-D animal ingredients in pet food.*** Lystn will address our ingredients in detail below.

- ***The FDA is claiming Lystn failed to file an RFR within 24 hours as required by the FD&C Act, Section 417. Again the FDA is inaccurate because the language in the Act states a reportable food is an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food <u>will cause serious adverse health consequences or death to humans or animals.</u>***

- ***The FDA's WARNING LETTER states that Lystn did not specify what corrective action, if any Lystn intends or proposes to take regarding our chicken products. <u>This is unequivocally false as evidenced below</u>. Lystn has supplied multiple action steps to address our chicken products in both previous correspondence to the FDA and our submitted Recall Strategy. Lystn has taken corrective actions such as additional quality assurance steps, while maintaining our position that there have been no violations proven that require additional actions.***

- ***The FDA threatens seizure and/or injunction against Lystn for alleged violations of law when the FDA themselves ignore the language contained in the federal law and instead strong-arms companies into firm-initiated recalls. In addition the FDA continues to "Misbrand" (stating misleading information) about the raw pet food industry on their website.*** The extent to which the FDA has attacked and forged unsupported claims against Lystn and its products seems intentional, an abuse of power and authority outside the language of the law in an attempt to defame Lystn as a raw pet food manufacturer to the general public and industry peers.

- ***The FDA is threatening assessment and collection of fees to cover FDA's costs for certain activities, including re-inspection-related costs to determine whether compliance has been achieved. Since the FDA has failed to prove any non-compliance, Lystn believes there should be no legal right by the FDA to charge such fees.***

<u>MORE DETAILED RESPONSE TO WARNING LETTER INCLUDING CORRECTIVE ACTION STEPS TAKEN</u>

<u>Paragraph 1 (page 1):</u> ***Regarding the referenced sample tested on October 5, 2015 please send hard copy dated results as we have no known testing or results on date October 5, 2015. We have FDA test results dated 10/8/15 however from the description and time line we are confident this is not our sample***; it references speciation of Salmonella Poly B which we have no hardcopy results of any positive Salmonella test from the FDA prior to this report. Receiving speciation testing before a confirmed positive would not make sense. According to your referenced samples it is not species indicated. We have a test result dated 10/13/15 indicating a positive Salmonella test result from product sampled 9/15/15, but no speciation results. We have test results dated 10/14/15 with product sample date of 9/4/15, this appears to be a reiteration of testing done by the State of Colorado and not actual testing by the FDA. We were told by the FDA it is an FDA violation only if proven by the FDA. Please send hard copy test result of sample # 862407 conducted by the FDA for presence of Salmonella and speciation test results. We had a verbal confirmation of a test on chicken patties testing positive for Salmonella on 9/16/15. ***There was confusion and <u>admitted loss</u> by your field agent of the sample when we requested speciation.***

<u>Response and Corrective Action(s) Steps Taken for Issues of Paragraph 1:</u>

- Lystn requested chain of custody to assure it was our product being tested. We are still waiting for that chain of custody information.

- Lystn prepared and submitted on November 17, 2015 to the FDA (Judith A. Patterson) our <u>155 Page Recall Strategy with multiple other documents addressing testing along with other relevant recall strategy issues.</u>

Paragraph 2 (page 1): FDA has expressed that their concerns with Salmonella-contaminated pet food are two-fold: safety of the animals consuming the product and safety of the humans in the same household. Indicating that it is more common to have human illnesses linked to contaminated pet foods than it is to have an animal illness.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 2:

- To address these statements objectively in regards to the actual health risk to an animal or human exposed to Salmonella contaminated food it is important to evaluate the particular food item in question, the handling and storage requirements of the food, as well as any safeguards present within the food matrix that could significantly reduce the probability for Salmonella infection to occur. Another very important consideration is the type of Salmonella serovar that is isolated from a food and the dose response relationship of the pathogen to humans. A review of the infectious dose levels of 6 different serovars of Salmonella on human volunteers proved to be quite large $>10^5$ CFU/ml (Kothary and Babu, J Food Safety 2001). Many studies have demonstrated that very low numbers of Salmonella cells are typically present in food, feed and environmental samples. However, the risk to human infection is implied because of the possibility of cell multiplication during transport and storage (Malorny et al. Appl Environ Microbiol 3/2008). It has been demonstrated that growth of Salmonella cells at temperatures below 6^oC (42^oF) does not occur (Malorny et al. Appl Environ Microbiol 3/2008). The current laboratory detection methods for determining the presence of Salmonella in a food matrix are very sensitive and require a preenrichment step to inhibit any growth of background microflora and revive any damaged or stressed Salmonella cells (e.g. ELISA based tests or PCR). Therefore, these methods may not accurately reflect the actual pathogenic load within the food matrix and its subsequent infection potential.

- Lystn's raw pet food employs several microbial hurdles during processing and is processed at temperatures below 0^oC (32^oF) and transported and stored at temperatures at or below -17^oC (0^oF). Additionally, we use ingredients produced by lactic acid bacteria (LAB), that are known to have a competing effect against pathogenic bacteria through the production of lactic acid and other antimicrobial metabolites such as bacteriocins (Stiles, Antonie van Leeuwenhoek 1996 and Alvarez-Siero, et al. Appl Microbiol Biotechnol 2016). According to the list in Table 2, 21 CFR 184, Lactic acid produced through fermentation is listed as a GRAS affirmed substance. Independent laboratory tests on the products confirmed positive for Salmonella (sample #862407 and sample #913964) that were further tested on Salmonella selective agar for enumeration, showed Salmonella growth of <10 CFU/g. In FDA's Guidance for Industry Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods (March 2012), footnote number 5 explains the phrase "adequately reduce" to mean reducing the presence of Salmonella to an extent sufficient to prevent illness and then proceeds to give the example of a potential 3 log Salmonella contamination, considering a safety factor of 2 log, and that a process adequate to reduce Salmonella spp. would be capable of reducing Salmonella by 5 logs per gram of food. Results from the direct plating of the Salmonella contaminated product on the selective media (XLT4 agar) when incubated at 35^oC for 48hrs, showed Salmonella growth to be <10 CFU/g. This result would be consistent with a product that is sufficient to prevent illness or the risk of Salmonellosis.

- Additionally, out of an abundance of caution and in an effort to bring it to the attention of the consumer who may be elderly or immune-compromised, Lystn voluntarily includes the following warning statement on ALL of the Lystn products we distribute (wording modified to address the specific type protein/product). "**Warning**: Not for human consumption. This is a raw product, it has not been pasteurized and may contain harmful bacteria." In addition, "**Safe Handling Instructions:** Keep raw poultry separate from other foods. Wash working surfaces, utensils, hands and any other items that touch or contact raw poultry with hot soapy water." We feel this statement will help eliminate any misuse or abuse of the product and is a clear and fair warning to consumers to use caution when using this product. The argument for the possible shedding of Salmonella in dogs fed a raw diet as a means of transmission has not been shown in the literature as a conclusive argument for the risk of infection to their caretakers. Studies have been highly variable across pet populations on the incidence, and the prevalence of isolation of Salmonella spp from the feces of healthy dogs and cats and is reported to be anywhere from 1-36% and 1-18%, respectively, regardless of the type of diet that is fed (Sanchez, et al. JAVMA 2002).

Paragraph 3 (page 1): The statement "Therefore, the above products are adulterated within the meaning of section 402(a) (1) of the Federal Food, Drug and Cosmetic Act (the act), 21 U.S.C. §342(a) (1)." continues to be reiterated by the FDA knowing it is incomplete, inaccurate and misleading in particular to Lystn's products as determined by the language in the act itself and also proven by our quantification testing. There has been no evidence presented to Lystn by the FDA of whether any existing conditions involving Lystn's products could contribute to a clinical situation that could expose humans or animals to a health hazard which is to be supported by scientific documentation and/or statements; no assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed; no assessment of the likelihood of occurrence of the hazard; and no assessment of the consequences or occurrence of the hazard.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 3:

- Under the FD&C Act (21 U.S.C. 342 (a)(1)) it states: "A food shall be deemed to be adulterated – (a) Poisonous, insanitary, etc., ingredients (1) If 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 foods does not ordinarily render it injurious to health." (underscored for emphasis). Lystn reported the company does not add Salmonella or any added substance that contained Salmonella to the chicken pet food and after Lystn conducted further testing quantifying the presence of Salmonella, which provided results indicating that our product is not harmful to health and that in support of our position we have a negative test result for the presence of Salmonella from the same lot number of the split sample taken months before any regulatory involvement, and we also have negative Salmonella test results for our vegetables and negative Salmonella test results for the eggs.

- Lystn conducted independent split sample testing by an independent certified laboratory and proper quantification testing techniques. Based on the intervention steps we take, including employing a competitive inhibition step, through the use of fermented ingredients in our formulas we have been able to demonstrate through repeated laboratory tests that do not kill off the background microflora (XLT4 agar) that **our competitive inhibition step (fermentation) is being validated as an inhibitory step preventing the growth and propagation of Salmonella, even under abusive conditions, such as temperature abuse or mishandling of the finished product thawing at room temperature without proper refrigeration.** Based on these results we are confident that exposure to the product will NOT cause serious health consequences to humans or animals, and in fact provides far better protection from the potential of any post-contamination or cross-contamination that may incur as a result of product mishandling by the end user and/or during the manufacturing process by plant workers or equipment.

Paragraph 4 (page 2): The statement "These inspections confirmed that you manufactured, introduced and delivered for introduction into interstate commerce, a food that is adulterated, and as such is prohibited under section 301 (a) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 331 (a)." is unsupported and contrary to the required findings of the Act to make such a claim as addressed in response to Paragraph 3 above.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 4:

- While Lystn has provided to the FDA undisputed test results, the facts that there has been no reports of illness and that the FDA has not met its obligations proving Lystn's ***food will cause serious adverse health consequences or death to humans or animals,*** in the interests of always striving to strengthen our quality control standards and processes, Lystn has taken steps by requiring completion of quality control checklists at the manufacturing plant to insure prescribed procedures are regularly followed including raw material ingredient prewashes with ozonated H_2O, cold temperature processing, inclusion of fermented ingredients to develop a competitive probiotic environment, and blast freezing of the finished products to maintain product quality through distribution.

Paragraph 5 (page 2): Where is the FDA seeing on Lystn's website a claim that cultured whey and montmorillonite control "harmful bacteria"? We have scanned and reviewed our entire website not finding this quote.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 4:
If the FDA can identify where this quote occurs (provide screen shot), Lystn will take steps to remove it from our website.

Paragraph 6 (page 2): The statement that "Your Chicken Formula dog food products are food under section 201 (f) of the Act, 21 U.S.C. § 321 (f), because they are articles used for food for animals." is another example of where the regulatory agencies, including the State of Colorado (where the investigation into this matter started) and the FDA contradict themselves. In addition, the FDA is now introducing a new violation claim for which Lystn, LLC has not previously received any paperwork on before the WARNING LETTER. By referencing Section 409 (a) (2) of the Act [21 U.S.C. § 348 (a) (2), the FDA is alleging unsafe food additives.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 4:

- The State of Colorado issued a STOP DISTRIBUTION ORDER IN THE MATTER OF THE DISTRIBUTION OF ADULTERATED **ANIMAL FEED** BY LYSTN, LLC. (bold font and underlining for emphasis). In FDA's "Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods" footnote No. 2 states "Direct-human-contact foods are animal foods that are intended for use in feeding animals in homes, petting zoos, agricultural fairs, and similar venues where they are likely to be directly handled or ingested by humans." Feeding animals in homes would certainly define cats, dogs and other type pet foods. Feeding animals in petting zoos, agricultural fairs and similar venues is the same food/feed as used in barns and pastures and seems to fit into animal feed.

- FDA's accusation that our Chicken Formula for dog products would be adulterated within the meaning of section 409(a)(2) of the Act [21 U.S.C. 348(a)(2)], because of the following ingredients: fermented cod liver, cultured whey, montmorillonite and vitamin E supplement, is highly confusing and seems rather unusual. With the exception of the qualifier "fermented" and "cultured", all of these ingredients have official AAFCO definitions and have been approved for use in animal feeds. If necessary, we will eliminate the reference to "fermented" cod livers and simply use cod livers and eliminate the word "cultured" from whey and declare the term just whey. Referring to the 2016 AAFCO official publication on page 375, definition **9.7 Animal liver**, can be used if it bears a name descriptive of its kind, in our case we are using cod liver. On page 413, definition **54.24 Whey**, is the product obtained as a fluid by separating the coagulum from milk, etc. There is no mention in this definition as to any restrictions on how or why it can be used as an ingredient. On page 447, **Table 73.1 Technical additives, Montmorillonite Clays** (21 CFR 582.1, which is GRAS status in non- medicated feeds) we are using it in our formula at less than 2% and we are using it as a processing aid and anti-caking agent. Lastly, page 472 definition **90.12 Vitamin E supplement**, is a feeding material used for its vitamin E activity. It must contain a minimum vitamin E activity of 10,000 IU per pound. The vitamin E oil we are using would fit under this definition. Therefore, we are certainly in disagreement with the FDA's determination in this scenario. Regardless, if the FDA deems it necessary, Lystn will remove the terms "fermented" from the cod livers and "cultured" from the reference of whey.

- As previously stated, while not a requirement for our meat and fowl proteins, in the interest of being cautious and forewarning to the end user we have on our chicken products packaging "**Warning:** Not for human consumption. This is a raw product, it has not been pasteurized and may contain harmful bacteria." In addition, "**Safe Handling Instructions:** Keep raw poultry separate from other foods. Wash working surfaces, utensils, hands, and any other items that touch or contact raw poultry with hot soapy water." The voluntary inclusion of such language highlights that Lystn goes well beyond other raw pet food diet manufacturers in making sure there is no misbranding or misrepresentation of the potential existence of unsafe food components that can be considered by immune compromised humans or parents of children with pets in their family. Lystn will continue to include the "Warning" and "Safe Handling Instructions" on our products out of an abundance of caution and full disclosure even though not required to do so.

Paragraph 7 (page 2): The FDA is inferring Lystn's ingredients are not recognized as safe under GRAS.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 7:

- The ingredients (whey, montmorillonite, vitamin E, and fermented cod livers [FDA has approval for fish liver]) are already defined and approved as safe (GRAS) ingredients.

- While in disagreement with FDA's position contained in the WARNING LETTER, in the spirit of compromise with the FDA, as previously stated, if the FDA deems it necessary Lystn will remove the words "fermented" and "cultured" in our ingredients.

Paragraph 8 (page 2): The FDA is reporting Lystn failed to file a Reportable Food Report (RFR) within 24 hours as required by the Food Drug and Cosmetic Act (FD&C), Section 417.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 8:

- ***Again the FDA is inaccurate because the language states a reportable food is an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.*** Again this is an unsupported claim by the FDA, ignoring contradictory test results, overlooking no reports of illness occurring, and unsupported by any differing test data or industry expert testimony to the contrary. A responsible party is required to submit a report to FDA through the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after determining that an article of food is a reportable food. Lystn has proven the products in question do not fit into a reportable food, while the FDA has failed to prove such a claim. ***When Lystn has repeatedly requested the FDA to supply such proof and if unrefuted Lystn would comply with the law, the FDA remains nonresponsive.*** When the FDA provides the requested proof, names and credentials of the individuals claiming Lystn's food will cause serious adverse health consequences or death to humans or animals, as well as addresses all of our previously documented concerns (such as providing chain of custody of tested products and complete test results), then Lystn will revisit whether the requirements of filing a Reportable Food Report have been met and if action is needed.

Paragraph 9 (page 2): The WARNING LETTER states that Lystn did not specify what corrective action, if any, Lystn intends or proposes to take regarding the products in question.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 9:

- This is again an incorrect statement by the FDA. Lystn has identified many steps taken, including preparing and submitting a 155 page Recall Strategy. Some actions to address immediate and time sensitive steps, while others are long term and applicable in the future. Just some of the actions taken by Lystn include:

  - In our September 28, 2015 letter to Sean Duke we listed 17 specific actions taken or proposed to be taken which was only a partial listing (see Letter).

  - In the same correspondence Lystn identified and explained our **Position on Salmonella Testing, Handling and Processing, and Mitigation** including addressing mitigation and control of pathogenic bacteria, proper handling and processing steps to reduce the risk of contamination, and how Lystn employs several intervention steps to continue to mitigate the risk of finished product contamination with pathogenic bacteria. Lystn takes seriously quality assurance and safety of all of our products, in terms of raw material ingredients, nutritional superiority, and processing and we consider all aspects of the food manufacturing chain from supplier inspection and verification, processing and distribution to end user handling.

    - First mitigation and control of pathogenic bacteria begins with the proper sourcing of livestock animals that are fed a species appropriate diet and allowed to flourish in an environment that is conducive to the ultimate health of the animals without the use of synthetic growth promotants, antibiotics, etc. Several USDA and independent studies have demonstrated that livestock animals raised in their native environments on pastures as opposed to those held in confined feeding operations, shed significantly less pathogens than their factory farmed counterparts. This is the first step, in our opinion, and a very important step to reduce pathogen contamination in the finished food supply.

    - Secondly, proper handling and processing steps at time of slaughter will reduce the risk of contamination. We feel that USDA/FSIS has implemented effective and measurable processing steps that significantly improve this process through the implementation of HACCP. Lystn has made the commitment to source nothing but raw material proteins harvested and processed through USDA certified and inspected facilities that process the same animals for the human food supply chain.

- Third, the manufacturing process of the finished product warrants its own intervention steps to continue to mitigate the risk of finished product contamination with pathogenic bacteria. We employ several intervention steps during this process. This includes raw material ingredient prewashes with ozonated H_2O, cold temperature processing, inoculation with fermented ingredients to develop a competitive probiotic environment, and blast freezing of the finished products to maintain product quality through distribution.

- Lystn prepared and submitted on November 17, 2015 to the FDA (Judith A. Patterson) our 155 Page Recall Strategy with multiple other documents.

- Lystn is now receiving Letters of Guarantee from poultry suppliers that product shipped to Lystn LLC is not adulterated or misbranded within the meaning of the poultry product inspection act.

- If identified by the FDA where Lystn, LLC is making any claim not supported by science, if unrefuted Lystn is willing to remove any such statements. It should be noted that there is extensive research available that raw cultured whey protects food from pathogenic bacteria. One could argue that there is more documentation and scientific proof suggesting the use of whey in food to inhibit bad bacteria providing a better approach as it continues to provide protection up to and including the point of consumption than the recommended High Pressure Pasteurization (HPP) processes suggested on the FDA website. The Safe Practices and Food Processing Section state that there is pressure resistant harmful bacteria, including Salmonella.

Paragraph 10 (page 2): Lystn takes very seriously our responsibility for assuring that Lystn's overall operation and any products manufactured and distributed are in compliance with the law.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 10:

- Lystn's extensive and completely responsive documentation and cooperation with the FDA up to receiving the March 17, 2016 WARNING LETTER highlights Lystn's past sincere efforts to comply with federal law and wishes of the FDA, but the FDA was unwilling to carry out their role and responsibilities as defined under federal law and honor their agreements (including previously agreed upon recall language), and instead continues to threaten product seizure and/or injunction.

- Lystn will continue to work with the FDA in trying to understand and resolve differences between what the federal and state laws require, and what is just a policy position of the FDA and/or state.

- As such, if a WARNING LETTER gets published as written with inaccurate and false claims, will the FDA remedy the situation by retracting the publication with notice of it being issued in error?

Paragraph 11 (page 3): Lystn has complied in responding within (15) working days of receipt of the WARNING LETTER. The letter states that if corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 11:

- Lystn has previously submitted to the FDA all the corrective actions referenced in the letter above, with the exception of the Letters of Guarantees referenced in response to Paragraph 9 which are on-going month-to-month.

Paragraph 12 (page 3): In reference to the accusation that Lystn is in violation of section 301(a) of the Federal Food, Drug, and Cosmetic Act that your inspections confirmed that we manufactured, introduced and delivered into interstate commerce, food that is adulterated, is of course predicated first on the fact the product is indeed adulterated, which requires under Section 21 U.S.C §342 (a) (1) that an added substance and quantified substance renders it injurious to health and adulterated and also that the use of or exposure to that food will cause serious adverse health consequences or death to humans or animals (SAHCODHA). Paragraph 12 also addresses re-inspection and other costs.

Response and Corrective Actions Step(s) Taken for Issues of Paragraph 12:

- Lystn is again requesting the name and credentials of the person(s) who will be endorsing such statements regarding Lystn's health hazard evaluation, as well as chain of custody and complete test results by the FDA.

- Lystn remains firm in its contention and concern that in the absence of the proper, scientific identification of a problem and "violation", the FDA is trying to force Lystn to "mitigate" a public health risk which does not exist. Since the "Warning Letter" seems unwarranted after a 117 day lapse in communication from the FDA and lack of clarification and documentation by the FDA, Lystn is questioning if the purpose of the addressed "WARNING LETTER" is to bring forth to light the present situation regarding the fore mentioned Lystn products to the public by posting the "WARNING LETTER" on the FDA website?

- Regarding the FDA assessing and collecting fees to cover FDA's costs for certain activities, it is Lystn's position that Lystn should not be charged for the FDA having to conduct additional inspection and testing related activities when the FDA was unable to prove a violation and perform correctly the original inspections and testing.

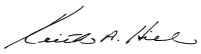
In conclusion, if Lystn intends in the future to make new claims on our packaging to customers and the general public regarding specific processes or ingredients utilized, we will take steps to validate our processes and ingredients through FDA recognized standards when specifically required by law and such validation processes are uniformly enforced by the FDA. In the meantime, we will continue sourcing our raw materials from highly regarded, highly monitored, health conscious farms. In addition, we will follow our Recall Strategy and continue to look for ways to improve. We also will take into consideration the different components required in the Food Modernization Safety Act when required. We believe the above statements satisfy the intentions of this letter, and the concerns of the addressed products.

If the purpose of the WARNING LETTER and our responses is to move towards closing this case by documenting proposed actions by Lystn to address concerns of the FDA, Lystn believes this correspondence, along with the previous referenced communications and submittals more than adequately address all concerns. While Lystn suspended a firm initiated recall for the many reasons documented, 21 CFR § 7.55 indicates that a recall (when and if required) will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Lystn believes it has undertaken action commensurate with the degree of the disputed hazard, and when combined with the unlikeliness that any of the product in question still exists given the significant time lapse and subsequent dates of products manufactured and distributed, the fact there have been no reported illnesses, as well as no proof provided by the FDA of the likeliness of presenting a health risk, and the fact that the quantity of such substance in such foods does not ordinarily render it injurious to health, for all these reasons Lystn believes both the actions of the FDA and Lystn's responses warrants termination of recall efforts by the FDA for these particular samples. The Act states a firm may request termination by submitting a written request and by way of Lystn's response to actions it has taken or intends to take in the future (such as the recall strategy), hereby respectfully requests such termination. The Act also states written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm. If the FDA is in disagreement, then we request more adequate explanations of what is required by Lystn, as well as the previously requested clarifications, questions and concerns raised by Lystn here and in the previous communications.

In the interest of brevity in addressing the specific WARNING LETTER issues, in concurrence this written response the FDA should consider all the extensive documentation previously submitted by Lystn as supplementing this response. Please feel free to contact me for further discussion, questions or concerns. Thank you for your time and consideration.

Sincerely,

Lystn, LLC



Keith A. Hill

President

Lystn, LLC

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