

# Beyond the Bowl

## Integrating raw feeding and science

# Lystn, LLC, Manufacturer of Answers Pet Food In Response to the January 14, 2019 FDA Warning Notice

This press release by Lystn, LLC d.b.a./ANSWERS Pet Food is in response to the January 14, 2019 Food Drug and Administration Warning Notice: **“FDA Cautions Pet Owners Not to Feed One Lot of A+ Answers Straight Beef Formula for Dogs Due to Salmonella”**.

Before addressing the history and investigation behind the events leading up to the FDA’s posting of this Notice, please allow Lystn to correct a number of errors in the FDA’s Notice:

- (1) The Best Use By Date (BUBD) is incorrectly listed as 20/08 20. The correct BUBD is 02/08 20.
- (2) The statement that Lystn has recalled the affected lot in Nebraska is not correct. Lystn stopped further distribution of the lot in question working with Lystn’s distributor, retail stores and the Nebraska Department of Agriculture who reported the follow-up that the product was removed from retail store shelves.
- (3) Just one reason Lystn has not implemented a nationwide recall is because the product was only tested by the State of Nebraska and Lystn for which the test results were contradictory addressed below, and not tested by the FDA.

The FDA Notice comments that the reason why the FDA issued this warning is because it (the product in question) represents a serious threat to human and animal health and is adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). It is important to note that neither Lystn nor any government agency has received any report of animal or human illness. Neither the State of Nebraska nor the FDA quantified the alleged finding of Salmonella which is just one factor for consideration when defining adulterated food under the FD&C Act. The FDA uses a Compliance Policy Guide which contains Nonbinding Recommendations of a “zero tolerance” of *Salmonella* for enforcement. In contrast to human consumed products inspected by the USDA, a certain percentage of Salmonella is allowed (some of the same sourcing Lystn buys as ingredients for its pet food). For just some of the reasons stated below, Lystn disagrees with the FDA “zero tolerance” policy, based upon our understanding of science and the FD&C Act. For additional information on our response to the FDA and Lystn’s position on these and other raw pet food industry issues, please visit our website. Additional information is forthcoming through continued updates.

Because Salmonella is prevalent throughout much of the food chain and in our environment, Lystn formulates ANSWERS Pet Food products to protect the pets and their owners from potential harmful bacteria using what is referred to as “Hurdle Technology”. One step of Lystn’s Hurdle Technology uses natural competitive inhibition through fermentation by inoculating our products, which favors growth of desirable (good) bacteria but inhibits the growth of pathogens (bad bacteria). This avoids destroying the benefits of good bacteria needed in the gut of the pets ingesting ANSWERS Pet food and continues to protect the pets post ingestion and the household environment from potential pathogens.

One (1) random test by the Nebraska Department of Agriculture was sampled 12/10/18 and revealed the presence of *Salmonella* in the Straight Beef Formula 4lb. Pounder for Dogs. Lystn requested a split sample of the product in question and while a confirmation of Salmonella was detected on the initial sample supplied by Nebraska, there was insufficient quantity to run all the quantitative tests. Lystn requested and received a subsequent larger quantity and all 4 samples tested negative for the presence of *Salmonella*. It is Lystn's belief (as well as our science advisors) that the initial sample sent from Nebraska may have been cross contaminated in the lab, transport or elsewhere and should not be considered a representative sample. Even if Salmonella was present in the initial sample, equally important was that the quantification of Lactic Acid Bacteria in the subsequent samples was significant in quantity (greater than Log 7) confirming that our fermentation process was working and therefore evaluated as a safe product by Lystn's team of scientists and advisors.

Lystn's Hurdle Technology and labeling addresses the concerns expressed by the FDA regarding product exposure and handling risks to children and immune compromised individuals, in that the good bacteria from the fermentation process continues to compete with bad bacteria, regardless of manner of exposure. Lystn's labeling conspicuously identifies the products as being in the raw state and states – "For Pet Use Only: Not for human consumption. This product has not been pasteurized and may contain harmful bacteria." The labeling also contains – "Safe Handling Instructions: Keep raw meat separate from other foods. Wash working surfaces, utensils, hands and any other items that come in contact with raw meat with hot soapy water."

We advised the FDA of Lystn's extensive third party test results and science based evaluation that the food is safe and not a public health risk, in accordance with the assessment of an independent Ph.D. science expert in concurrence with Lystn's science team. Nevertheless, the FDA proceeded to issue this Warning Notice without further consultation with Lystn.

Many of our distributors, customers, and retailers alike understand Lystn's use of competitive inhibition through the process of fermentation to protect our foods from pathogens. But, if after presenting our customers with our views, if a customer is uncomfortable with an ANSWERS' product, they may return it (or any unused portion) to the place of purchase for a full refund. The Straight Beef Formula 4lb. Pounder for Dogs product comes in a cardboard milk carton box marked with lot code 2018 and a Best Use By Date (BUBD) of 02/08 20 sticker on the carton. The above referenced lot number and BUBD Lystn product was distributed at various times from 8/17/18 to 9/14/18 and sold through retail stores within the United States.

ANSWERS Pet Food continues to be at the forefront as a leader in transparency and is committed to keeping you informed. We are in the process of creating a page on our website for the web and social media for our customers to go see the latest information concerning state and federal regulatory matters applicable to ANSWERS Pet Food and the raw pet food industry. To learn more about ANSWERS, our unique process, and the raw pet food industry, please visit our website at <http://www.answerspetfood.com> (<http://www.answerspetfood.com>).

The above comments and observations by Lystn are the current view and understanding of Lystn and not intended to be a statement of law nor contain all details that may apply. Thank you for time and understanding.

Lystn, LLC, Manufacturer of Answers Pet Food

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