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"I heard your company had a recall..."

So begins the majority of our correspondence lately, be it by phone or email.

Today we want to take the opportunity to explain the differences between a Stop Sale, a Warning Letter and a Recall. As you no doubt have heard by now, the FDA is on a mission to persecute manufacturers of real, fresh foods for pets. These "very small businesses" make excellent targets because most of them are unaware of their legal rights and become subject to the very real intimidation factor when faced with FDA officials who knock on the door, flash their badges and spout off code references while pushing their way inside our facilities to conduct "investigations." Even the use of the word "investigation" serves to put us on the defensive, and we don't even know what we've been accused of. We small businesses exist to fill a need; the vast majority of us got started in this line of work out of a passion for helping to keep pets healthy through good food. Our daily lives are devoted to this mission; the very last thing any of us wants to have happen is harm caused to someone's beloved pet by a product we have put our heart and soul into producing with the very best ingredients and the very safest manufacturing processes.

So how is the FDA attempting to rid the world of fresh pet food? As mentioned previously, they have made up their own rule called Zero Tolerance, as part of what is called a Guidance for Industry. Any of FDA's Guidance Policies is prefaced with some fine print that states it is not law and is not binding. This is important because it means they cannot enforce it. It is merely their opinion. However, they are doing precisely that—enforcing it—despite the fact this is not legal. Wait, what? How can they get away with that? Most of us have been caught unaware and unprepared for this onslaught of harassment interrupting our efforts to keep our businesses operating day to day. And some companies have succumbed to the pressure and been bullied into performing unnecessary recalls, or even into shutting down completely. The good news is, we "very small businesses" dedicated to producing the best possible fresh-food pet foods, are banding together to stand up and Just Say No to the FDA. No, we will not rush to do a recall just because they claim one sample of our product tested positive for *Salmonella*, when we have been given absolutely no proof, and their sampling and testing procedures have been blatantly violated. No, we will not hand over confidential information like names and contact information for our customers! And Yes, we will fight back the only way we can: with truth and information to debunk the irrational panic and fear they are attempting to create among pet owners.

The least harmful thing they can do is persuade a state's department of agriculture to issue a Stop Sale Order. In fact, this happened to us recently. But before we could even tell you about it, they followed up with a Warning Letter, and that is what we focused on in our last update. A Stop Sale is issued at the state level, and it states that no one (retail store, or manufacturer) may continue to sell the named product. In our case, we believe the Stop Sale was a result of us asking a lot of questions about the ONE sample they took from a local store, that they claimed tested positive for *Salmonella*. According to their own protocol for sampling products, they are required to collect TEN identical packages from the same lot number. They are also required to provide what is known as a "split sample," which means they save some of the contents of those ten packages and allow us to conduct our own testing on it, at a lab of our choosing. In this case, since they failed to collect the required amount, they were unable to provide us with the split sample we requested. By issuing the Stop Sale, they hoped to track down and acquire more packages so they could correct their mistake. In our case, no location still had the product in question in their freezers. This particular batch was made and sold last November/December. It is long gone. If there were going to be any problems with it, they would have surfaced way before now. Imagine how much time and money was wasted sending inspectors from store to store, searching for something they never found. And despite all of this, they still escalated to the next step.

A Warning Letter is the next step, and we have now had 2 of these in the last 6 months. A Warning Letter is the latest tactic FDA is using to attack small companies, by issuing the letters without any warning to the company ahead of time. We learned about the letter from our customers, when our phone started ringing as a result of its publication. Thus there is zero chance of us defending ourselves or trying to work toward a resolution with FDA before creating mass pandemonium among the pet owning public. This is exactly what they hope for when publishing their letters. But please know this: **A Warning Letter is not a recall!** Semantics are extremely important in this case, and it is quite frustrating when misinformation gets spread around such that the rumor mill transforms a Warning Letter into a Recall. This is also what has happened to us, both times. For the record, we still have never had a recall, in 20+ years of serving up your pets' meals. And yet the public is very quick to jump to conclusions and assume that our product was recalled. Even some of those websites that pet owners subscribe to, to alert them of current recalls, are erroneously reporting that our products were recalled when they were not. We are reaching out to those sites to help educate them on the difference, to try to prevent unnecessary fear and anger on the part of pet owners who accuse us of being dishonest or of trying to hide or cover up a recall.

The most harmful thing to any company is a Recall. A Recall happens when a product has been found to cause harm. At least, that's what a Recall is supposed to be for—to alert the public to actual, known harm, and to get back any remaining packages of the product in question so that it cannot harm anyone else. Any responsible company would act promptly to do this, if and when it is warranted. However, when NO harm has come to anyone from the product in question, and there is NO basis because FDA has failed to follow their own protocol, no company wants to go through issuing a Recall.

FDA can use a strongarm tactic to try to persuade a company to do a "voluntary" recall. They base this on their illegal Zero Tolerance opinion and questionable sampling/testing practices. In other words: no proof. Some companies have succumbed to this pressure and issued unnecessary recalls. Some have even ended up financially broken and had to shut down completely. Others are standing up and refusing, because we know that our products are safe and there is no proof to the contrary. One of the best votes of confidence a product can receive is when the manufacturer continues to use it for personal use. Our staff feeds every batch we make to our own pets, without hesitation, and with never one ill effect.

Once any company experiences a Recall, they are on an FDA Hit List that puts them even further under the microscope, subjecting them to even more scrutiny and torment. A Recall is like a permanent black mark that causes irreparable damage to a company's reputation. Not to mention the public embarrassment and shame suffered by well-meaning business owners who would never intentionally harm anyone's pets. Don't forget our entire careers are centered around keeping pets healthy! There is far more likely to be *Salmonella* present in kibble and other inferior grade products than you will ever encounter in fresh-food ingredients originally intended for human consumption, properly handled and minimally processed. And that is our entire reason for doing what we do every day.

Finally, we leave you with this thought to bear in mind. The financial impact of any of these three things—Stop Sale, Warning Letter, Recall—on a small company, even if there is no actual recall, can be devastating. The company is forced into a position of defending itself, spending countless hours on public relations. The company desperately wants to demonstrate goodwill to its customers, so is forced to refund money for product that is perfectly good—maybe even already consumed, without incident (because everyone wants something for free)—that has not even been recalled. Technically they are not obligated to do this. But in the cancel culture world we live in, not doing so can be just as damaging. How many hits can one company sustain and remain in business?