



February 21, 2020

VIA U.S. MAIL

Francis and Ronda Archangelo
38277 Ocean Vista Drive, Unit 1187
Seblyville, DE 19975

Dear Mr. and Mrs. Archangelo:

Thank you for taking the time to write to Acella Pharmaceuticals, LLC. First and foremost, please accept my deepest condolences for the loss of your beloved pet, Mimi. I have been the proud parent of numerous pets throughout my lifetime – from working dogs to cuddly cats – and each one has a special place in my heart.

When I first received your letter, I must admit I was as angry as I was saddened. It is widely known that many formulations of liquid Gabapentin intended for human use, including Acella's, contain xylitol. It is upsetting that a veterinarian would not know better than to prescribe it. A quick search of the terms "liquid Gabapentin dogs" on Google came up with the following articles warning of its use in dogs, including one from the American Veterinarian Medical Association:

- <https://www.avma.org/blog/eliminate-xylitol-canine-prescriptions>
- <https://dogtime.com/dog-health/53089-gabapentin-dogs-uses-dosage-side-effects>
- <https://vcahospitals.com/know-your-pet/gabapentin>
- <https://www.petmd.com/dog/care/gabapentin-dogs-what-you-need-know>
- <https://www.veterinaryplace.com/dog-medicine/gabapentin-for-dogs/>

The tragedy is that, with this type of information available at a veterinarian's fingertips, there is no reason for Mimi to have been put at risk.

I want to stress, here, that there is also no expectation for you to have known about the dangers of using human liquid Gabapentin in dogs. Our relationships with our veterinarians are built on a trust that the veterinarian understands the unique physiology of our pets and how various medications might affect them. Our reliance on their education and experience, and their resulting advice, is inherent to this relationship. While it may be appropriate in some cases for veterinarians to prescribe human drugs for use in animals, it is incumbent upon them to be educated on how to safely do so. More importantly, it is their obligation to review and understand the known risks, cautions or instructions in connection with prescribing any human drug for use in an animal under their care.

Our label is approved by the FDA for use in humans only. Since xylitol in the amount contained in our liquid Gabapentin product is not known to have an adverse impact on human health, the FDA has not approved any warning on our product with respect to xylitol. We are not permitted by the FDA to unilaterally change our label without their permission. However, as dog



lovers ourselves, we at Acella do not want to see another dog be given our liquid Gabapentin product due to a mistake by a veterinarian or pharmacist. While we cannot be sure that the FDA will allow the change, we will ask the FDA to permit us to add a warning to our product label to note that our product contains xylitol and should not be administered to dogs. This process will take time, but if it will help prevent these types of mistakes in the future, it is certainly worth the effort on our end.

You also asked for more specific information regarding the xylitol content of our product. It is our position that no amount of our liquid Gabapentin product should be given to a dog. Our product is intended for human use only, and any attempt to manipulate the dosing to control the quantity of xylitol ingested by a dog is dangerous and ill-advised. There are numerous tablet forms of Gabapentin on the market that do not contain xylitol. There may even be forms of liquid Gabapentin specifically formulated and approved by the FDA for use in animals that would be less likely to contain xylitol. To the extent that the veterinary toxicologist you have consulted from Michigan State University would like more information on our product in connection with a certified animal drug study, please ask him or her to contact us directly, and we may be able to provide more detailed information under an appropriate nondisclosure agreement.

Finally, with respect to reporting Mimi's incident to the FDA, Acella is required to report adverse drug events with respect to human use of its products, including Gabapentin. However, the FDA process for reporting adverse effects in animals is managed by a separate division of the FDA, the Center for Veterinary Medicine and is specific to drugs approved for use in animals. Because our product is not approved by the FDA for use in animals, our product is not subject to the Center for Veterinary Medicine's reporting requirements.

I wish you the very best in your efforts to get other manufacturers of liquid Gabapentin to add a warning to their labels. I am happy to let you know how the FDA responds to our requested label change. In the meantime, our thoughts are with you and your family.

Very truly yours,

A handwritten signature in blue ink, appearing to read "Harold A. Deas, Jr.", is positioned above the printed name.

Harold A. Deas, Jr.
Chief Executive Officer