

The Honorable Kathleen Sebelius  
U.S. Department of Health and Human Services  
200 Independence Ave. SW  
Washington DC 20201  
Via e-mail



April 1, 2013

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we are requesting the opportunity to meet with you personally to describe the actions taken against us and to try and resolve this problem. The time now being spent on non-productive efforts to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Would it not be better for everyone involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We hope that you will look favorably on the possibility of meeting with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people. We look forward to the possibility of meeting with you.

Sincerely,

A handwritten signature in black ink, appearing to read "John H. Hnatio". The signature is written in a cursive style with a large initial "J" and "H".

John H. Hnatio, EdD, PhD  
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB  
Dr. Dale Berkley, DHHS Counsel  
Ms. Elizabeth Dickinson, Chief Counsel, FDA