

Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993



**Via e-mail**

April 22, 2013

Dear Commissioner Hamburg:

We are writing this letter to you at the suggestion of the Small Business Administration's Office of the National Ombudsman.

We are a small business that produces computer automated risk management tools for the food industry. Several weeks ago, we filed a complaint with the Office of the National Ombudsman for Small Business because employees of the Food and Drug Administration (FDA) stole our small business' intellectual property, used it to duplicate our entire suite of computer software tools and are continuing to try and force us out of business.

After we filed our complaint with the National Ombudsman for Small Business the matter was raised from the Office Chief Counsel, FDA to the Office of General Counsel of the Department of Health and Human Services (HHS) for a high level review. Unfortunately, the resolution of the matter has reached an impasse.

When we first reached out to the FDA Chief Counsel, Ms. Elizabeth Dickinson, in early January 2013, we asked for the opportunity to sit down with her as a responsible government official to discuss the situation. At that time, we believed that reasonable people could sit down together and have a thoughtful discussion to resolve the serious matters that have arisen in this case.

Instead, both the FDA Chief Counsel and the Office of General Counsel, HHS, quickly "circled the bureaucratic wagons" and abandoned all notion of conducting any type of good faith review of the matter. At this time, they are still pursuing the path of mounting a legal defense to protect the FDA and those employees in the Agency guilty of conducting the wrongdoing in the first place.

Attached please find a letter we wrote to Secretary Sebelius that provides additional details on the current status of the situation for your information.

As you can see from reading our letter to Secretary Sebelius, the situation has escalated from our original request to simply sit down with a responsible official at the FDA for a thoughtful discussion on how we might work together to resolve the serious issues that have arisen here to an outright campaign by the FDA to completely crush our business.

At this juncture, the FDA continues to steal our intellectual property, market and give away for free the computer software tools they duplicated based on our intellectual property; give official government endorsements of the products produced by our competitors and engage in a program to “black list” our small business across the food industry.

This whole matter is of grave concern to us not only because it is destroying our lives, reputations and livelihoods but also because it threatens to severely shake the confidence of the American people in the premiere federal agency responsible for the safety of the drugs Americans use and the food we all eat. The further escalation of this matter is not in the best interests of the FDA as you pursue the unique and special mission of protecting the health and safety of the American people.

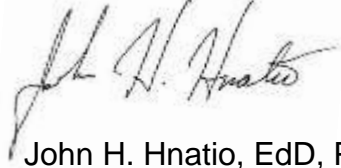
In all of my correspondence to senior officials in both the FDA and HHS, I have repeatedly offered to sit down with you in order to have a thoughtful discussion on how we can work together as a team to resolve the serious issues that have arisen here in a way that serves the best interests of the American people, the vital role played by the FDA in regulating the drug and food industries and the small businesses across our great country that are essential to create jobs for Americans and fuel the scientific innovation critical to maintaining the nation’s competitive edge. Our offers have been rebuffed at every turn.

Again, we are reaching out to find someone in the federal bureaucracy who is capable of making the evidence-based decisions that are necessary to break the current circle of self-defeat that we are now engaged in. The time being wasted on denying the truth of what has really happened here can be much better spent on creating a safer food supply for the American people.

We hope that you will accept our offer to engage with you in a thoughtful dialogue about the devastating implications of direct government competition on small businesses like ours and how we can work together to prevent the shattering consequences we have experienced from ever happening to another small business or entrepreneur. If we do not support small businesses on America we will lose the very science and technology innovation that FDA must have on order to fulfill its own mission.

If you have any questions or desire any further information please feel free to contact me at telephone number 240.439.4476 x-11. I look forward to the possibility of hearing from 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

(1) Attach: 4-19-2013, Letter to Secretary Sebelius