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



## October 1, 2013

## **Dear Secretary Sebelius:**

We are a small business located in Frederick, Maryland. In January of this year we reached out to the Food and Drug Administration (FDA) to work with us to resolve a matter involving the plagiarism of our research and the FDA duplication of our company's computer software.

Since January of last year, we have written to you and other officials in both the Department of Health and Human Services (HHS) and in the FDA many, many times. The purpose of those letters was to request the opportunity to sit down with you to try and resolve the matter. You have not responded to our numerous requests for a meeting.

In August 2013, we reached out to our congressional representatives to ask for their help in arranging a meeting with a senior HHS official to discuss HHS policy with respect to direct competition by the FDA with small companies to force them out of business.

We have received very disturbing feedback that HHS is telling others that we did not cooperate with the HHS-OGC investigation of the matter conducted in April 2013. These statements are patently untrue. Attached please find the information that we shared with our congressional representatives trying to correct the record.

In fact, it was HHS Counsel that refused to cooperate by refusing to undertake as part of the HHS investigation our concerns that the FDA was unfairly competing with our small company by stealing our trade secrets and duplicating our products. Instead, HHS Counsel insisted that the only issue involved was "patent infringement" while he refused to consider the other equally important concerns that were brought to his attention. We believe he did this intentionally to leave our small company with no alternative for redress since we do not have the resources to pay for a long and costly lawsuit.

In our last letter to you of September 10, 2013, we respectfully requested that employees of the FDA and HHS cease and desist making misleading statements regarding our company and the professionalism of our personnel. Further efforts by HHS and FDA personnel to blacklist our company serve no useful purpose in trying to resolve this matter. In this letter we are respectfully requesting that FDA and HHS personnel stop making false statements to Congress.

This is the tenth time that we have written to you. In each of our prior letters, we requested the opportunity to sit down with you to try and resolve this matter in a fair and reasonable way. Again, we repeat the same request. I am sure that you agree the time being spent on this situation could be better used working to create a safer food supply for the American people.

Most respectfully yours,

John H. Hnatio, EdD, PhD Chief Science Officer

cc: Margaret Hamburg, FDA