

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



Via e-mail

April 19, 2013

REF: April 1, 2013, Letter from Dr. Hnatio to Secretary Sebelius

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. On April 1, 2013, we wrote to you asking for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA).

In my letter to you I explained that the Food and Drug Administration has stolen our small business' intellectual property and duplicated our entire commercial offering of computer software tools. As a result the government is forcing us out of business. In our letter we requested the opportunity to meet with you personally to describe the actions being taken against us and to try and resolve this problem. But we never received any response from you. **We are very concerned that members of your own staff may be intentionally withholding our letters from you.**

I have been informed by the National Ombudsman for Small Business that this entire matter was elevated from the Office of Chief Counsel in the FDA to the Office of General Counsel of the Department of Health and Human Services (HHS) for a high level review. Please be advised that our interactions with both FDA and HHS legal counsels have been at an impasse for several months. Instead of conducting a good faith review that could lead to resolving this matter before it escalated to this point they have "circled the wagons" in order to defend the FDA's own errors in this matter.

Over this entire period, the FDA has continued to market and give away at no cost to the public and the food industry the tools they duplicated by stealing our intellectual property and trade secrets. **No timely actions are being taken by either the Department of Health and Human Services or the FDA to work with us to prevent the further public distribution of our intellectual property including our trade secrets.** Every day that our trade secrets are further disseminated to the public by the FDA just serves to put another nail in the coffin of our small business.

For all of the above reasons, we are officially requesting that HHS immediately direct the FDA to stop the further marketing of FQTQ FDA-duplicated software tools and immediately remove all of the FDA-duplicated FoodQuestTQ LLC computer software tools from the official FDA government website pending the resolution of this matter. This formal request includes the immediate removal from the FDA website of the following specific information and software tools that are based on the intellectual property and trade secrets that the FDA has stolen from us, namely the FDA:

1. *Food Protection Plan*;
2. *Food Defense Plan Builder*;
3. *Food Defense Mitigation Strategies Database*;
4. *iRisk*, and;
5. *FREE-B*.

For the record, we would like to note that it is highly possible that the FDA has duplicated other products based on our intellectual property and trade secrets that we are not yet aware of.

This past week we discovered that the FDA has publicly endorsed the products of one of our industry competitors, *Tyco Integrated Systems*. (See: <http://www.foodmanufacturing.com/videos/2013/04/food-defense-strategy-part-1-assess>). It is both highly unethical and unlawful for any federal agency to engage in such conduct. Engaging in such activities is specifically prohibited by the Office of Government Ethics and under 5 C.F.R. Part 2635: Standards of ethical conduct for employees of the executive branch and under numerous other statutes.

We also find this most disturbing based on the fact that FoodQuestTQ was singled out by the FDA and excluded from participating in a December 12, 2012, industry workshop held by the FDA to obtain industry inputs on one of the software tools the FDA duplicated based on the intellectual property they stole from us. FDA officials lied when they told the Grocery Manufacturer's Association that we were prohibited from attending the workshop because the FDA did not want to endorse any commercial products. Clearly, this was nothing but a ruse by the FDA to prevent us from finding out that they were stealing our intellectual property. We found out after the workshop that *Tyco Integrated Systems* was invited by the FDA and actually attended the same FDA workshop we were prohibited from attending.

For the above reasons, we are formally requesting that HHS immediately stop endorsing the commercial products of our competitors in reprisal against us for expressing that the FDA has, in fact, stolen our intellectual property, duplicated our products and is forcing us out of business.

We have also discovered that the FDA is holding a major workshop with the food industry on April 30, 2013, to unveil for the food industry FDA's *Food Defense Plan Builder* that duplicates our Food DefenseTQ and Food Defense Architect Tools based on the intellectual property stolen from us by the FDA. By holding such a public forum, the FDA is not only continuing to engage in the theft of our intellectual property but also further distributing to the public at large our commercial trade secrets.

For the above reasons, we are formally requesting that HHS instruct FDA to cancel their food industry workshops on Food Defense Plan Builder to be held on Tuesday, April 30, 2013, at the Food Safety Summit that is being held at the Baltimore Convention Center in Baltimore, Maryland.

This last week a major business partnership critical to the future of our small company was unexpectedly terminated. The agreement was terminated by our industry partner because they feared FDA reprisal in obtaining future contracts from the FDA or being blacklisted by FDA themselves as the result of their association with FoodQuestTQ LLC. Earlier, in December 2012, a member of the FDA Food Defense Team widely distributed, off her government computer, a news article written by FoodQuestTQ about the FDA endorsed "C.A.R.V.E.R. + Shock" risk assessment tool. In the article FoodQuestTQ raised doubts about the utility of the "C.A.R.V.E.R. + Shock" method as it is currently being used by the FDA to assess risks to the U.S. food supply. The FDA budget contains a \$13 million appropriation to support the use of the "C.A.R.V.E.R. + Shock" method.

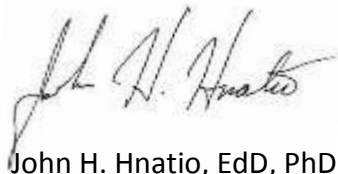
For the above reasons, we formally request that HHS direct the FDA to stop "blacklisting" FoodQuestTQ in the food industry. We also request that the FDA place an apology at their main web site publicly apologizing for this type of conduct. If the FDA is allowed to continue "blacklisting" us in this way there will be no further hope for the survival of our small business.

In our previous letter to you of April 1, 2013, we requested a meeting with you to try and resolve this problem. We expressed our feeling that 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. We asked you the question, "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?"

Again, we 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".

John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Dr. Dale Berkley, HHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA
Ms. Laurie Lenkel, Small Business Ombudsman, FDA