APRIL 29, 2015

THIS CONSTRUCTIVE NOTICE IS SERVED ON THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION (FDA) PURSUANT TO THE UNIFORM COMMERCIAL CODE OF THE STATE OF MARYLAND AND THE LAWS OF THE UNITED STATES OF AMERICA

IF THIS AFFIDAVIT IS NOT PROPERLY REBUTTED WITH A COUNTER-AFFIDAVIT WITHIN FORTY FIVE (45) CALENDAR DAYS FROM THE DATE OF ITS SERVICE, ALL PARAGRAPHS NOT DENIED SHALL BE CONFESSED AFFIRMED, BY SUCH DEFAULT, AND SHALL BE ACCEPTED AS DISPOSITIVE, CONCLUSIVE FACTS, BY THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION (FDA). WHEREIN THE COMMISSIONER OF THE FDA, CONTRACTORS AND SUB-CONTRACTORS OF THE FDA OR ANY PROPERLY DELEGATED AUTHORITY HAVE BEEN GIVEN NOTICE AND HAD THE OPPORTUNITY AND "FAILED TO PLEAD." ALL COUNTER-AFFIDAVITS MUST BE SIGNED WITH THE VALID LEGAL NAME, TITLE AND ORIGINAL SIGNATURE OF THE COMMISSIONER OF THE FDA.

AFFIANT: JOHN HNATIO

This Affidavit and all attached documents have been made a part of the Public Record and will be used for evidence in the administrative and judicial proceedings at law, or equity regarding this case. All of these documents are maintained in Claimant's Administrative File. This affidavit and exhibits are posted on the John Galt Program for Investigative Studies web site at (http://jgpis.org/) for further public notice and to provide the Food and Drug Administration (FDA) the opportunity to rebut each of the forty-two (42) claims appearing below.

AFFIDAVIT OF TRUTH

- 1. The Food and Drug Administration (FDA) is headquartered in Silver Springs, Maryland, in the United States of America. [UCC EXHIBIT 1]
- 2. The FDA engages in commerce by entering into agreements and contracts with the private sector. [UCC EXHIBIT 2]
- 3. The FDA is subject to United States procurement statutes, codes and laws including, but not limited to, 5 CFR Part 2635; Title 41 U.S. Code 253; Title 48, Chapter 1 U.S. Code; Title 18 U.S. Code § 1031; P.L. 96-303; Title 18 U.S. Code §§ 654; 654; 641, and 1832. [UCC EXHIBIT 3]
- 4. The FDA is subject to the patent laws of the United States, including but not limited to, Title 35 U.S. Code- Patents. [UCC EXHIBIT 4]
- 5. The United States issues patents through the United States Patents and Trademarks Office (USPTO) which are valid in the United States and its territories. [UCC EXHIBIT 5]

- 6. From 2002 through the summer of 2006, JOHN H. HNATIO conducted a program of doctoral research at The George Washington University. [UCC EXHIBIT 6]
- 7. On October 28th, 2003, JOHN H. HNATIO applied to the USPTO for a patent (Application No. US 10/694,024) based on his doctoral research. [UCC EXHIBIT 7]
- 8. In August 2006, JOHN H. HNATIO's doctoral dissertation was published and registered with USPTO as copyrighted material belonging to JOHN H. HNATIO. [UCC EXHIBIT 6]
- 9. On June 12, 2007, JOHN H. HNATIO submitted USPTO Patent Application No. US 11/808,580 claiming preference to his 2003 invention disclosure. [UCC EXHIBIT 8]
- In November 2007, the FDA issued their "National Food Protection Plan."
 [UCC EXHIBIT 9]
- 11. The "National Food Protection Plan," contains written expressions of ideas contained in JOHN H. HNATIO's doctoral dissertation. [UCC EXHIBIT 9] (add plagiarism analysis)
- 12. The "National Food Protection Plan," includes ideas contained in JOHN H. HNATIO's 2003 patent application and his then pending July 2007 USPTO patent application. [UCC EXHIBIT 9]
- 13. Title 18 USC § 1905 prohibits government employees from revealing business confidential information provided to them by the private sector that relates to trade secrets, processes, operations, style of work, or apparatus. [UCC EXHIBIT 10]
- 14. Over the period 2006 to 2012, FDA officials received a series of proprietary briefings from JOHN H. HNATIO concerning the development of his food risk management tools based on his doctoral dissertation. [UCC EXHIBIT 11]
- 15. These briefing materials contained JOHN H. HNATIO's patented ideas and trade secrets that HNATIO developed as he reduced his inventions to practice. [UCC EXHIBIT 11] (add most recent trade secrets/patent analysis)
- 16. The briefings were marked as containing proprietary information. [UCC EXHIBIT 11]
- 17. On March 25, 2009, JOHN H. HNATIO submitted a proprietary unsolicited proposal to the FDA Joint Institute for Food Safety and Nutrition (JIFSAN) (Dr. Julianna Ruzzante) and the Center for Food Safety and Applied Nutrition (CFSAN) (Dr. Robert Buchanan) for the co-development of HNATIO's patented food risk software. [UCC EXHBIT 12]

- 18. The unsolicited proposal contained patented ideas and trade secret information JOHN H. HNATIO developed as he reduced his invention to practice. [UCC EXHBIT 12] (add most recent trade secrets/patent analysis)
- 19. The unsolicited proposal was marked as containing proprietary information. [UCC EXHIBIT 12]
- 20. The unsolicited proposal was rejected by JIFSAN and CIFSAN. [UCC EXHIBIT 12]
- 21. In April 2011, the FDA released their "Food Defense Mitigation Strategies Database," food risk management software that contained the patented ideas and trade secret information developed by JOHN H. HNATIO as he reduced his inventions to practice. [UCC EXHIBIT 13]
- 22. The "Food Defense Mitigation Strategies Database" food risk management software was published on the World Wide Web. [UCC EXHIBIT 13]
- 23. In June 2011, the FDA released their "Food Response Emergency Exercise Bundled or FREE-B," food risk management software that contained the patented ideas and trade secret information developed by JOHN H. HNATIO as he reduced his invention to practice. [UCC EXHIBIT 14]
- 24. The "Food Response Emergency Exercise Bundled or FREE-B" food risk management software was published on the World Wide Web. [UCC EXHIBIT 14]
- 25. On January 24, 2012, USPTO Patent No. US 8103601 B2 issued (with priority to Application No. US 11/808,580) with Affiant listed as inventor. [UCC EXHIBIT 15]
- 26. On May 16, 2012, the FDA executed a Military Interdepartmental Purchase Request (MIPR) from the Department of Defense Chemical Warfare/Chemical and Biological Defense Information Analysis Center (CBIAC) to fund a subcontract with Valbrae Technologies. [UCC EXHIBIT 16]
- 27. Valbrae Technologies was granted a non-competitive subcontract to produce FDA's "Food Defense Plan Builder" tool software. [UCC EXHIBIT 16]
- 28. On October 2, 2012, Mr. Jody Menikheim, head of FDA's Food Defense Team, stated that their "Food Defense Plan Builder," tool accomplished the same purpose as JOHN H. HNATIO's prior developed risk management software but was not as sophisticated. [UCC EXHIBIT 17]

- 29. On October 2, 2012, JOHN H. HNATIO offered a \$1.00 per year license for FDA employees to use JOHN H. HNATIO's suite of computer tools. The FDA did not respond. [UCC EXHIBIT 18]
- 30. In October 2012, the FDA released their "iRisk," food risk management software that contained the patented ideas and trade secret information developed by JOHN H. HNATIO as he reduced his inventions to practice. [UCC EXHIBIT 19] (add most recent trade secrets/patent analysis)
- 31. The "iRisk" food risk management software was published on the World Wide Web and copyrighted as the property of the FDA. [UCC EXHIBIT 20]
- 32. On December 12, 2012, the FDA held a food industry meeting at the Headquarters of the Grocery Manufacturer's Association (GMA) in Washington, D.C., to obtain inputs on their new "Food Defense Plan Builder," software tool. [UCC EXHIBIT 21]
- 33. JOHN H. HNATIO and his company FoodQuestTQ were prohibited by the FDA from attending the meeting. [UCC EXHIBIT 21]
- 34. FDA stated that no one but food processors would be allowed to attend the meeting in order to avoid unfair competition. [UCC EXHIBIT 21]
- 35. Two direct competitors of JOHN H. HNATIO's company, Tyco Integrated Systems and Leavitt Partners attended the FDA meeting on December 12, 2012. [UCC EXHIBIT 21]
- 36. On May 18, 2013, the FDA released their "Food Defense Plan Builder," food risk management tool that accomplished, by FDA's own admission, the same purposes as JOHN H. HNATIO's prior developed risk management software. [UCC EXHIBIT 22] (add most recent trade secrets/patent analysis)
- 37. The "Food Defense Plan Builder" food risk management software was published on the World Wide Web and copyrighted as the property of the FDA. [UCC EXHIBIT 20]
- 38. 5 C.F.R. Part 2635, Subpart A, General Provisions, requires employees of the U.S. Government to avoid appearances of, and never engage in, actual conflicts of interest. [UCC EXHIBIT 23]
- 39. FDA and other U.S. Government attorneys did not recuse themselves from investigating JOHN H. HNATIO's allegations of fraud, waste and abuse that were being made directly against them. [UCC EXHIBIT 24]
- 40. The Code of Ethics for Government Service (P.L. 96-303) states that the allegations fraud, waste and abuse being made by JOHN H. HNATIO against the FDA attorneys other

FDA employees and FDA contractors involved should have been referred by government counsel to the Office of Inspector General for an independent investigation. [UCC EXHIBIT 25]

- 41. The Code of Ethics for Government Service (P.L. 96-303) states that the allegations fraud, waste and abuse being made by JOHN H. HNATIO against the FDA attorneys other FDA employees and FDA contractors involved should have been referred to the Office of Inspector General for an independent investigation. [UCC EXHIBIT 25]
- 42. The Inspector General of the Department of Health and Human Services (DHHS-OIG), the parent agency of the FDA, was kept fully aware of the situation by JOHN H. HNATIO and provided supporting evidence of fraud, waste and abuse by the FDA directly to the DHHS-OIG but he did meaningfully investigate the matter. [UCC EXHIBIT 26]

Affiant incorporates by reference a comprehensive report of investigation that includes a computer library of documentary evidence supporting each of the individual statements of truth as set forth in paragraphs one (1) through forty-two (42), above, that was provided to the DHHS-OIG. The report dated November 28, 2014, entitled, "The Case of FoodQuestTQ" and exhibits can be directly accessed on the World Wide Web at http://www.jpgis.org

I solemnly affirm under the penalties of perjury and upon personal knowledge that the contents of the foregoing paper are true to the best of my knowledge and belief.

County of: Frederick State of: Maryland

JOHN HNATIO

Witnesseth the above signature affixed to this document on this day of April 29, 2015

Notary Signature and Official Seal on this day of April 29, 2015
