Mr. Daniel Levinson
Inspector General
Department of Health and Human Services
330 Independence Ave., S.W.
Room 5250
Washington, DC 20201

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Reference: November 20, 2013, Letter of Referral from the National Ombudsman for Small Business, Small Business Administration

Dear Mr. Levinson:

On November 20, 2013, we received a letter from Mr. Brian Castro, the National Ombudsman for Small Business of the Small Business Administration. In that letter (copy attached) Mr. Castro advises that he has referred our matter to your office for possible investigation.

To very briefly re-cap the situation, we are a small business that is being forced out of business in the face of direct competition by the U.S. Government. The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) are plagiarizing our research, pirating our patented ideas and stealing our trade secrets. Using this information the FDA has duplicated our products and is giving them away for free to industry. As a direct result, the bottom has dropped out of our sales and we are being forced out of business.

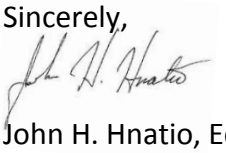
As we have attempted to resolve the matter with both FDA and HHS, we have discovered the possibility of very serious violations of the law to include violations of Article 1, Clause 8 of the United States Constitution, i.e. the copyright clause; breaches of confidentiality of FoodQuestTQ-owned business confidential information by FDA employees contrary to the protections guaranteed under Title 18, USC, and; the potential obstruction of justice by a legal counsel representing HHS and the FDA employees who were engaged in the alleged wrongdoing. In May of 2013, we wrote a detailed case study chronicling the situation. A copy of this document is attached for your review.

Over many months we have been working with our elected representatives on Capitol Hill to seek their intervention in this matter because it involves such serious indications of potential fraud, waste and abuse. But Mr. Castro's referral of the matter to you is fortuitous because it opens the door to being able to resolve this unfortunate situation more quickly and we plan to cooperate and assist you in any investigation that you may decide to undertake. In this regard, we have done significant work in developing the enclosed investigative guide to help the various oversight and investigations Subcommittees in the House and Senate to better understand the situation and to possibly assist them in an investigation of the matter.

What follows are a series of simple “yes” and “no” questions the answers to which will reveal a truthful baseline on which to proceed in this matter. Truthful responses to the questions can be easily discerned without prejudice of opinion by examining the documented record as contained in the ten exhibits. All of the documents contained in the exhibits should be available from the HHS Office of General Counsel. But, if you would like us to provide copies of the ten exhibits referenced in the enclosed materials we will be pleased to provide them to you.

Thank-you very much for considering Mr. Castro’s referral of our case to your office for possible investigation. We look forward to helping you in any way we can to resolve this matter.

Sincerely,



John H. Hnatio, Ed, PhD
Chief Science Officer

cc:

Kathleen Sebelius, HHS
Margaret Hamburg, FDA
Brian Castro, SBA

Investigatory Guide for the Subcommittee

A series of questions regarding:

A. Whether the HHS OGC "investigation" of FoodQuestTQ's concerns is was lawful, complete, and impartial.

   1. Questions relating to the April 26, 2013 HHS OGC legal brief sent to FoodQuestTQ regarding the HHS OGC "investigation" of FoodQuestTQ's concerns.

   2. Whether FoodQuestTQ failed to cooperate with HHS/FDA.

   3. Whether FoodQuestTQ attempted to provide HHS/FDA with information needed to conduct a complete investigation.

   4. Whether FDA allegations that FoodQuestTQ was unreasonable in their request to protect the company's intellectual property.

B. Whether the FDA including any contractors or subcontractors have infringed on the FoodQuestTQ patent, used FoodQuestTQ intellectual property and or plagiarized the copyrighted research of Dr. Hnatio, the Chief Science Officer of FoodQuestTQ.

   1. Whether the FDA plagiarized Dr. Hnatio's 2006 doctoral dissertation.

   2. Whether the FDA Food Protection Plan is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or FoodQuestTQ owned intellectual property.

   3. Whether the FDA Food Defense Plan Builder is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or FoodQuestTQ owned intellectual property.

   4. Whether the FDA Food Defense Mitigation Strategies Database is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or FoodQuestTQ owned intellectual property.

   5. Whether the FDA iRisk computer software tool is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or FoodQuestTQ owned intellectual property.

   6. Whether the FDA FREE-B tool is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or FoodQuestTQ owned intellectual property.

C. Whether the FDA has retaliated against FoodQuestTQ for resisting the government's actions in this matter.

1. Whether the FDA action to preclude FoodQuestTQ from participating in an industry workshop to demonstrate their competing commercial product was motivated by FDA's desire to avoid commercial competition.

2. Whether the FDA action to preclude FoodQuestTQ from participating in an industry workshop was in retaliation for the publication of a FoodQuestTQ article laying out alleged weaknesses in FDA's approach to vulnerability assessment and food defense.

3. Whether the FDA publicly endorsed the commercial products of Tyco Integrated Systems.

4. What the involvement of Leavitt Partners (now the Acheson Group) was in the matter of FoodQuestTQ.

5. Whether the FDA "blacklisted" and/or FDA employees engaged in any forms of defamation involving FoodQuestTQ.

D. The role played by the FDA Office of Acquisitions and Grants Services (OAGS) in the FoodQuestTQ matter.

E. The role played by the HHS/FDA Offices of Small Business and Disadvantaged Utilization in the FoodQuestTQ matter.

F. The role played by the National Ombudsman for Small Business of the Small Business Administration in the FoodQuestTQ matter.

G. Whether the FDA has directly competed with FoodQuestTQ.

List of Exhibits

EXHIBIT 1: Letter from Mr. Dale Berkley, Esq., Office of the General Counsel, Department of Health and Human Services dated April 26, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXHIBIT 1-A: E-mail from Ms. Ariel Seeley, Esq., Office of the Chief Counsel, Food and Drug Administration dated March 14, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXHIBIT 1-B: E-mail from Ms. Ariel Seeley, Esq., Office of the Chief Counsel, Food and Drug Administration dated, March 14, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXHIBIT 1-C: E-mail from Ms. Ariel Seeley, Esq., Office of the Chief Counsel, Food and Drug Administration dated, March 22, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXHIBIT 1-D: Note from Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC, dated March 2, 2013, to Ms. Ariel Seeley, Esq., Office of the Chief Counsel, Food and Drug Administration.

EXHIBIT 1-E: Screen shots from FDA web site showing copyright annotations for the FDA Food Defense Plan Builder and the iRisk computer software tools

EXIBIT 1-F: Highlighted portion of letter from Mr. Dale Berkley, Esq., Office of the General Counsel, Department of Health and Human Services dated April 26, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXIBIT 1-G: Highlighted portion of letter from Mr. Dale Berkley, Esq., Office of the General Counsel, Department of Health and Human Services dated April 26, 2013, to Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC.

EXHIBIT 2: Numerous letters to FDA and HHS officials from Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC requesting the opportunity for a meeting to resolve the dispute.

EXHIBIT 3: Letters from Dr. John Hnatio, Chief Science Officer, FoodQuestTQ LLC to the Office of Government Ethics, the National Ombudsman for Small Business and other federal officials requesting their assistance.

EXHBIT 4: Briefing for the National Ombudsman for Small Business dated March 19, 2013, containing 25 specific examples of the intellectual property that FoodQuestTQ alleges is being used by the Food and Drug Administration without permission.

EXHIBIT 5: Detailed technical crosswalk of the contents of the FDA Food Protection Plan, Food Defense Plan Builder, the Food Defense Mitigation Strategies Database, iRisk and FREE-B tools against Dr. Hnatio's patent dated March 8, 2013.

EXHIBIT 6: FoodQuestTQ offers to demonstrate their tools to the OGC-HHS in return for a similar demonstration of FDA's tools.

EXHIBIT 7: EXHIBIT 7-A: Dr. Hnatio's doctoral dissertation dated summer 2006.

EXHIBIT 7-B: Dr. Hnatio's patent. Complexity Systems Management Method, Patent No.: US 8,103,601 B2. Date of Issue: January 24, 2012. United States Patent and Trademark Office, Washington, D.C.

EXHIBIT 8: Information memorandum to U.S. industry from FoodQuestTQ LLC dated June 3, 2013, entitled, "Twenty Specific Examples of Projectioneering LLC and FoodQuestTQ LLC Intellectual Property Being Used by the Food and Drug Administration (FDA) without Permission."

EXHIBIT 9: EXHIBIT 9-A: E-mail from Mr. Warren Stone to Mr. Bruce Becker, titled "URGENT GMA MTG Dec 12 Food Defense Plan Builder" dated December 11, 2012, in which FDA precludes the participation of FoodQuestTQ personnel.

EXHIBIT 9-B: E-mail from Mr. Colin Barthel, Battelle memorial Institute dated November 27, 2012, indicating that only food processors would be welcome at the FDA sponsored workshop.

EXHIBIT 9-C: Web link to FDA public endorsement of Tyco Integrated Systems.

EXHIBIT 10: EXHIBIT 10-A: Article by FoodQuestTQ issued on December 6, 2012. The article raises questions about the utility of FDA's C.A.R.V.E.R. plus Shock vulnerability assessment tool.

EXHIBIT 10-B: Screen shot of Mail Chimp automated monitor of interest in the FoodQuestTQ article published on December 6, 2012.

Subcommittee Questions for HHS/FDA

A. The purpose of these questions is to guide the investigation of whether the HHS OGC "investigation" of FoodQuestTQ's concerns was a legal activity, legally conducted, complete, fair and accurate.

1. The Subcommittee staff has carefully reviewed the April 26, 2013, letter from the Office of General Counsel (OGC), Department of Health and Human Services (HHS) to FoodQuestTQ, including all exhibits. To assist the Subcommittee in our investigation, please answer the following questions.

Q-1 Please have Mr. Dale Berkley, OGC-HHS, answer the following question for the record. When Mr. Berkley conducted his "investigation" of the FoodQuestTQ matter did he do so in the capacity as a legal defense counsel for the FDA and the FDA employees alleged to have engaged in the wrongdoing?

☐ Yes

☐ No

Q-2 Please have Mr. Dale Berkley, OGC-HHS, answer the following question for the record. When Mr. Berkley conducted his "investigation" of the FoodQuestTQ matter and learned of the serious allegations including possible criminal violations of Title 18 USC, did he immediately recuse himself and refer the matter to the Department of Health and Human Services (HHS), Office of Inspector General for proper investigation as required by law?

☐ Yes

☐ No

Q-3 Please have Mr. Dale Berkley, OGC-HHS, answer the following question for the record. Did Mr. Berkley, as the result of his "investigation" of the FoodQuestTQ matter, subsequently extend FDA lawyer client privilege to those employees alleged to have participated in the wrongdoing in the first place?

☐ Yes

☐ No

Q-4 Please have Mr. Dale Berkley, OGC-HHS, answer the following question for the record. Does Mr. Berkley fully understand his ethical obligations and duties as a practicing attorney and Member of the Bar to avoid potential (real or perceived) conflicts of interest that may befoul legitimate law enforcement investigations of criminal activity?

☐ Yes

☐ No

Q-5 Please have Mr. Dale Berkley, OGC-HHS, answer the following question for the record. Did Mr. Berkley understand as a practicing attorney and Member of the Bar his obligations not to engage in the obstruction of justice in his "investigation" of the FoodQuestTQ matter?

☐ Yes

☐ No

Q-6 Please have Ms. Ariel Seeley, FDA counsel, answer the following question for the record. Did Ms. Seeley, indicate to FoodQuestTQ that the information FoodQuestTQ provided to the Office of Chief Counsel of the FDA about their patent was sufficient to make a determination in the matter?

☐ Yes

☐ No

Q-7 Please have Ms. Ariel Seeley, FDA counsel, answer the following question for the record. Did Ms. Seeley decline FoodQuestTQ's offer to provide additional information about the history of the FoodQuestTQ patent, how it was reduced to practice in a suite of tools, and the specific trade secrets that FoodQuestTQ alleges are now being used by the FDA without permission?

☐ Yes

☐ No

Q-8 Please have Ms. Ariel Seeley, FDA counsel, answer the following question for the record. Did Ms. Seeley, as FDA staff counsel, ever indicate to FoodQuestTQ that both the FDA Office of Chief Counsel and the office of General Counsel of the Department of Health and Human Services (OGC-HHS) were acting as attorneys representing the best interests of HHS/FDA in the matter and not those of FoodQuestTQ?

☐ Yes

☐ No

Q-9 If the answer to Question 2, above is "Yes" then please answer the following question. Under such circumstances, was it at all unreasonable for FoodQuestTQ to conclude that the matter was being handled by the FDA Office of Chief Counsel and the OGC-HHS as an adversary legal dispute?

☐ Yes

☐ No

Q-10 Did FoodQuestTQ give members of the FDA Food Defense Team a guided on-line tour of the National Food Protection Collaboratory™ web site?

☐ Yes

☐ No

Q-11 Please have Ms. Ariel Seeley, staff counsel FDA, answer the following question for the record. Did FoodQuestTQ specifically invite Ms. Seeley and the FDA Office of Chief Counsel to visit their web-site known as the National Food Protection Collaboratory™?

☐ Yes

☐ No

Q-12 Did anyone from the FDA Office of Chief Counsel or the OGC-HHS ever visit the National Food Protection Collaboratory™ web site to review the non-exclusive descriptions of the workings of the FoodQuestTQ tools that are publicly available there?

☐ Yes

☐ No

Q-13 Please have Ms. Ariel Seeley, staff counsel FDA, answer the following question for the record. Did FoodQuestTQ offer to provide the Office of Chief Counsel FDA with an explanation of the "nuts and bolts" of their technology and "to set up a demonstration for the folks in your office so that we can walk you through our Food Defense Architect, Food DefenseTQ, FEAST and FREE tools"?

☐ Yes

☐ No

Q-14 Irrespective of the HHS OGC's focus on patent infringement in the FoodQuestTQ matter, did the OGC-HHS "investigation" of the FoodQuestTQ matter specifically include the other intellectual property that FoodQuestTQ alleges is currently being used by HHS/FDA without permission?

☐ Yes

☐ No

Q-15 Please attach the letter, e-mail or other correspondence from FoodQuestTQ in which FoodQuestTQ refused to provide non-exclusive copies of the works they allege the HHS and FDA have used without their permission.

Q-16 Is it customary for legal firms or attorneys to take up to 25% and sometimes more than 50% of the proceeds of settlements reached in intellectual property cases when clients cannot afford to pay for their legal expenses "up-front"?

☐ Yes

☐ No

Q-17 Is it unusual for lawsuits being heard before the Federal District Court of Claims in patent infringement cases to take many years to resolve because of filled court dockets and other reasons?

☐ Yes

☐ No

Q-18 Are the FDA Food Protection Plan, the Food Defense Mitigation Strategies Database, Food Defense Plan Builder, iRisk and FREE-B tools copyrighted by the government or otherwise considered the intellectual property of the Food and Drug Administration?

☐ Yes

☐ No

Q-19 Did the FDA conduct due diligence, e.g., a literature searches, prior to publishing the Food Protection Plan, the Food Defense Mitigation Strategies Database, Food Defense Plan Builder, iRisk and FREE-B tools

☐ Yes

☐ No

Q-20 Is the FDA willing to make all documentation, source code and descriptive materials for the FDA Food Protection Plan, the Food Defense Mitigation Strategies Database, Food Defense Plan Builder, iRisk and FREE-B tools available to the public upon request?

☐ Yes

☐ No

Q-21 Please attach a list of the statutes, laws, and HHS/FDA policies that were used by the HHS OGC to justify denying FoodQuestTQ access to the workings of the Food Defense Mitigation Strategies Database, Food Defense Plan Builder, iRisk and FREE-B tools?

Q-22 Did the OGC-HHS conduct due diligence in examining the history of the intellectual property that FoodQuestTQ alleges is being used by the FDA without permission?

☐ Yes

☐ No

Q-23 Please provide a dated copy of the FDA's due diligence analysis of the history of both the patent and the other intellectual property FoodQuestTQ alleges is being used by the FDA without permission. In the event that no record of such an analysis exists please so signify below.

☐ There is no record of any analysis of the history of both the patent and the other intellectual property FoodQuestTQ alleges is being used by the FDA without permission.

Q-24 Did the ideas in the FoodQuestTQ patent and other intellectual property briefed to the FDA Food Defense Team pre-date 2007?

☐ Yes

☐ No

Q-25 When the FDA began building Food Defense Plan Builder, did the FDA consider the implications this action would have on small businesses in general and FoodQuestTQ in particular?

☐ Yes

☐ No

Q-26 Was the FDA Office of Procurement and Grant Services consulted before the FDA Food Defense Team began to build Food Defense Plan Builder?

☐ Yes

☐ No

Q-27 Did the FDA Office of Procurement and Grant Services (OAGS) concur on the decision to build the FDA Food Defense Plan Builder tool?

☐ Yes

☐ No

Q-28 If so, please attach a copy of the signed or initialed document for the review.

Q-29 Did the FDA conduct the due diligence necessary to assure that the Agency was not infringing on existing patents or other privately held intellectual property including copyrights before they began to build Food Defense Plan Builder?

☐ Yes

☐ No

Q-30 Please attach a copy of the due diligence analysis conducted by the FDA for the FDA Food Defense Plan Builder software tool. If no record of a due diligence analysis exists please so signify below.

☐ No written analysis was conducted.

Q-31 Did the FDA conduct due diligence to assure that the Agency was not infringing on any existing patents or other privately held intellectual property including copyrights before they began the production of the FDA Food Protection Plan, the Food Defense Mitigation Strategies Database, iRisk and FREE-B tools?

☐ Yes

☐ No

Q-27 Please attach a copy of the due diligence analysis conducted by the FDA or HHS for the FDA Food Protection Plan, the Food Defense Mitigation Strategies Database, iRisk and FREE-B tools. If no record of such an analysis exists please so signify below.

☐ No FDA or HHS record that such an analysis was conducted exists.

Q-28 Please have Mr. Jody Menikheim answer the following question for the record. Did FoodQuestTQ ever express their concerns to Mr. Menikheim that the FDA Food Defense Planner tool was duplicating their Food DefenseTQ and Food Defense Architect tool?

☐ Yes

☐ No

Q-29 Please have Mr. Jody Menikheim answer the following question for the record. Did Mr. Menikheim and other members of the FDA Food Defense Team meet with Dr. John Hnatio and other FoodQuestTQ personnel where Mr. Menikheim and members of his staff were given a comprehensive briefing and demonstration of the FoodQuestTQ LLC software tools?

☐ Yes

☐ No

Q-30 Please have Mr. Jody Menikheim answer the following question for the record. Did Mr. Menikheim and other members of the FDA Food Defense Team subsequently meet with Dr. John Hnatio, Dr. Barton Michelson, Mr. William Wright and Mr. David Park where he and members of his staff were given a comprehensive briefing and demonstration of the FoodQuestTQ LLC software tools?

☐ Yes

☐ No

Q-31 Please have Mr. Jody Menikheim answer the following question for the record. Did FoodQuestTQ express their concern to Mr. Menikheim that the FDA's work Battelle Memorial Institute to develop the Food Defense Plan Builder was resulting in direct competition with FoodQuestTQ's existing Food DefenseTQ and Food Defense Architect products before FDA published Food Defense Plan Builder at their official government web site?

☐ Yes

☐ No

Q-32 Please have Mr. Jody Menikheim answer the following question for the record. Did Mr. Menikheim have a telephone conversation with Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ and others, in which Dr. Hnatio specifically expressed the company's concerns about the FDA competing directly with FoodQuestTQ?

☐ Yes

☐ No

Q-33 Please have Mr. Jody Menikheim answer the following question for the record. Prior to the December 12, 2012, FDA workshop at GMA Headquarters, did Mr. Menikheim have a telephone conversation in which Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, asked him specifically about the nature and purpose of the upcoming FDA sponsored workshop and FDA' s new food defense plan builder tool.

☐ Yes

☐ No

Q-34 Please have Mr. Jody Menikheim answer the following question for the record. During the alleged conversation with Dr. Hnatio referred to above, did Dr. Menikheim discuss FDA's Food Defense Plan Builder tool as providing an easier method to understand C.A.R.V.E.R. plus Shock?

☐ Yes

☐ No

Q-35 Please have Mr. Jody Menikheim answer the following question for the record. Did FoodQuestTQ offer Mr. Menikheim and the FDA a $1 a year license for FDA employees to use the company's patent, trade secrets and other intellectual property?

☐ Yes

☐ No

Q-36 Please have Mr. Jody Menikheim answer the following question for the record. Did he confer with any other FDA official about the FoodQuestTQ offer of a $1 a year license to the FDA to use FoodQuestTQ's intellectual property?

☐ Yes

☐ No

Q-37 If so, please attach a list of the names with contact information for each of the individuals Mr. Menikheim conferred with about the FoodQuestTQ offer of a $1 per year license.

Q-38 Please have Mr. Jody Menikheim answer the following question for the record. Did he confer with any other FDA official about the concerns expressed to him by FoodQuestTQ that the FDA was competing with the small business?

☐ Yes

☐ No

Q-39 If so, please provide the names and contact information for each of the individuals Mr. Menikheim conferred with about the FoodQuestTQ's concerns that the FDA was unfairly competing with their company.

Q-40 Please have Mr. Jody Menikheim answer the following question for the record. At the time Mr. Menikheim contacted Mr. Warren Stone of the Grocery Manufacturer's Association and excluded FoodQuestTQ from participating in the FDA sponsored workshop, was Mr. Menikheim aware of FoodQuestTQ's concerns that FDA's Food Defense Plan Builder and FoodQuestTQ's Food Defense Architect were both designed to help the food industry build food defense plans?

☐ Yes

☐ No

Q-41 Is the FDA familiar with the term “patent poaching?”

☐ Yes

☐ No

Q-42 Do the HHS and FDA support President Obama’s initiatives to stop the exploitation of small businesses through the use of unfair intellectual property practices?

☐ Yes

☐ No

Q-43 Does the FDA have a policy that precludes the Agency from engaging in “patent poaching” against small businesses? If so, please attach a copy of the Agency’s policy.

☐ Yes

☐ No

Q-44 Did FoodQuestTQ write numerous letters to senior officials in both HHS and FDA asking to meet with senior officials to resolve this matter?

☐ Yes

☐ No

Q-45 Did anyone from the FDA or HHS ever meet with FoodQuestTQ in response to the company’s numerous letters?

☐ Yes

☐ No

Q-46 The OGC HHS refers to other letters written by FoodQuestTQ to various sources in the FDA and other government agencies. Please attach all “cc” copies of these letters received by either the FDA or HHS for review.

Q-47 Does the HHS OGC find it the least bit peculiar that FoodQuestTQ developed a tool called "FREE" only to be followed shortly thereafter by an FDA tool with the very similar name "FREE-B"?

☐ Yes

☐ No

Q-48 Please provide the precise date that the name "FREE-B" was first reduced to written form as part of the FDA FREE-B tool. Please insert the date below.

_ _ / _ _ / 20_ _

Q-49 Please provide the relevant portion of the above FDA dated document for review. If no record exists when the term "FREE-B" was first reduced to written form please so signify below.

☐ No record exists.

2. The Subcommittee is investigating the HHS OGC allegations that FoodQuestTQ was uncooperative in trying to resolve this matter. FoodQuestTQ has provided the staff with numerous letters requesting to meet with HHS and FDA officials over a period of six months in which they repeatedly asked to sit down and resolve the matter. To assist the Subcommittee investigation, please answer the following questions.

Q-1 Did FoodQuestTQ offer to sit down with FDA and HHS officials to resolve the matter?

☐ Yes

☐ No

Q-2 Please insert below the total number of times FoodQuestTQ wrote a letter to HHS-FDA requesting a meeting to sit down and resolve the matter with HHS-FDA over the six-month period of December to the current time, below.

FoodQuestTQ wrote to the FDA and HHS ____ times over the period December 2012 to June 2013 asking for a meeting.

Q-3 Please provide copies of the HHS and FDA responses to <u>each</u> of FoodQuestTQ's letters above requesting a meeting to resolve the matter. If you did not respond to FoodQuestTQ's requests to meet with them to resolve the matter please so signify below.

☐ HHS and FDA never responded to FoodQuestTQ's letters about the company's desire to hold a meeting.

Q-4 Please attach a copy of both FDA's and HHS's Agency policies as they relate to answering correspondence from the public.

3. The Subcommittee staff is investigating the HHS OGC allegations that FoodQuestTQ refused to provide the information needed to conduct a complete investigation. FoodQuestTQ LLC has provided the staff with numerous documents showing that they offered to share critical information relating to this matter with the Office of General Counsel HHS. Among these documents include offers to provide:

   a) Specific examples of the intellectual property allegedly stolen by the Food and Drug Administration, and;

   b) A detailed technical "crosswalk" demonstrating the alleged FDA infringement on their patent.

To assist the Subcommittee investigation, please answer the following questions.

Q-1 During the course of FDA's and HHS's review of this matter did HHS or FDA ever take FoodQuestTQ up on their offer to provide these documents?

☐ Yes

☐ No

Q-2 If so, please attach a copy of the letter, e-mail or other correspondence in which HHS/FDA responded to the offer by FoodQuestTQ. If the FDA Office of Chief Counsel FDA and the HHS OGC never responded to FoodQuestTQ's offer please so signify below.

☐ Neither the FDA Office of Chief Counsel FDA nor the HHS OGC responded to FoodQuestTQ's offer to demonstrate their tools if FDA agreed to demonstrate their tools in return.

Q-3 Did the Office of the National Ombudsman for Small Business provide the HHS OGC a copy of the briefing prepared by FoodQuestTQ that identified 25 specific examples of the intellectual property that FoodQuestTQ alleges are being used by the FDA without permission?

☐ Yes

☐ No

Q-4 Did the HHS Office of General Counsel legal opinion in this matter specifically address the extensive analysis of the alleged plagiarism of Dr. Hnatio's research that subsequently appeared in the FDA Food Protection Plan?

☐ Yes

☐ No

Q-5 Did the HHS Office of General Counsel legal opinion in this matter specifically address the 25 specific examples of the intellectual property that FoodQuestTQ alleges were stolen by the Food and Drug Administration that were provided to the National Ombudsman for small business?

☐ Yes

☐ No

Q-6 Did the HHS Office of General Counsel legal opinion in this matter specifically address and the detailed FoodQuestTQ technical "crosswalk" demonstrating the alleged FDA infringement on the FoodQuestTQ patent?

☐ Yes

☐ No

4. The Subcommittee is investigating HHS OGC allegations that FoodQuestTQ was unreasonable in their request to protect the company's intellectual property. The April 26, 2013, letter from the HHS OGC to FoodQuestTQ indicates that FoodQuestTQ refused to provide access to their tools without receiving "a contractual commitment to an unspecified disclosure of FDA information." To assist the Subcommittee investigation, please answer the following questions.

Q-1 Did FoodQuestTQ offer to demonstrate their tools to the OGC-HHS in return for a similar demonstration of FDA's tools?

☐ Yes

☐ No

Q-2 Irrespective of the issue of alleged patent infringement, was FoodQuestTQ's request for the OGC-HHS to consider, as part of a negotiated non-disclosure agreement, the protection of the company's trade secrets and other intellectual property unreasonable?

☐ Yes

☐ No

Q-3 Was it unreasonable for FoodQuestTQ to request that the OGC-HHS "investigation" go beyond the issue of patent infringement to also consider the issue of direct government competition with their small business?

☐ Yes

☐ No

Q-4 Was it unreasonable for FoodQuestTQ to request that the OGC-HHS investigation include potential irregularities involving acquisition and procurement activities relating to the implementation of Federal Acquisition Regulations, the FAIR Act and OMB Circular A-76?

☐ Yes

☐ No

Q-5 Does the FDA adhere to Office of Management and Budget and Office of Government Ethics Guidance regarding the utilization of private sector resources? The office of Government Ethics guidance appears here for review.

☐ Yes

☐ No

Q-6 Does the HHS General Counsel concur with HHS counsel's opinion that the FoodQuestTQ's concerns as specified in questions 3 through 5, above, are "minor pretenses" as stated in the OGC-HHS April 26, 2013, letter to FoodQuestTQ?

☐ Yes

☐ No

Q-7 Do the HHS and FDA follow the Federal acquisition and procurement regulations in all of their contracting activities?

☐ Yes

☐ No

Q-8 Do the HHS and FDA make reasonable cost comparisons when deciding to build products "in house" when similar or better products are already commercially available?

☐ Yes

☐ No

Q-9 Is the FDA Office of Acquisitions and Grant Services (OAGS) responsible for overseeing the procurement and acquisition activities of the Agency's Food Defense Team.

☐ Yes

☐ No

Q-10 Please attach for the Subcommittee's review a copy of the cost determination judgment made by the FDA Office of Acquisitions and Grant Services (OAGS) used to justify the FDA decision to build Food Defense Plan Builder at taxpayer expense when a cheaper and better commercial alternative was already available? If no written record exists please signify below.

☐ The FDA Office of Acquisitions and Grant Services (OAGS) has no written record of a cost determination judgment.

Q-10 Please attach a copy of the FDA Office of Acquisitions and Grant Services (OAGS) justification made pursuant to government ethics statues before allowing Mr. George Hughes, Senior Advisor, Counterterrorism & Intelligence to publicly appear in a Tyco Integrated Systems produced marketing video on the role of food defense. If no record of such approval exists please signify below.

☐ The FDA Office of Acquisitions and Grant Services (OAGS) has no written record justifying the public FDA endorsement of Tyco Integrated Systems.

B. The Subcommittee is investigating whether the FDA has infringed on Dr. Hnatio's patent, used FoodQuestTQ intellectual property and plagiarized the copyrighted research of Dr. Hnatio, the Chief Science Officer of FoodQuestTQ.

1. The Subcommittee is investigating the possibility that the FDA including its contractors and subcontractors have plagiarized Dr. Hnatio's 2006 doctoral dissertation. In 2006, the George Washington University published a doctoral dissertation written by Dr. John Hnatio, Chief Science Officer of FoodQuestTQ based on a five year program of research he conducted beginning in 2001. The document was copyrighted at the time of its publication in 2006. The five years of research detailed in the dissertation was the basis for Dr. Hnatio's 2007 patent. Appendix A of the dissertation specifically addresses how the research can be applied to the safety of the food supply. To assist the Subcommittee investigation, please answer the following questions.

Q-1 In the dissertation does Dr. Hnatio specifically address how his ideas and methods can be used to address threats and risks across the food supply?

☐ Yes

☐ No

Q-2 Does Dr. Hnatio's 2003-2006 dissertation research specifically address the use of the threat and risk continuum of deterrence, detection, prevention, i.e., the FDA uses the substitute term of "intervention", response and mitigation?

☐ Yes

☐ No

Q-3 Does Dr. Hnatio's dissertation research specifically address the indicators and warnings of adverse events, i.e., FDA use the substitute term "signals"?

☐ Yes

☐ No

Q-4 Does Dr. Hnatio's dissertation research specifically address vulnerability and consequence as measures of inherent risk, i.e., probability of occurrence?

☐ Yes

☐ No

Q-5 Does Dr. Hnatio's dissertation specifically address the idea of organized step-by-step countermeasures to address system risks, i.e., the FDA uses the substitute term "mitigating strategies"?

☐ Yes

☐ No

Q-6 Does Dr. Hnatio's dissertation specifically address the creation and use of simulated exercises and scenarios to create multidisciplinary awareness of risks and risk countermeasures through the use of structured exercises?

☐ Yes

☐ No

Q-7 Does Dr. Hnatio's dissertation specifically address the identification and prioritization of high risk areas across all critical infrastructures including the food supply system?

☐ Yes

☐ No

Q-8 Does Dr. Hnatio's dissertation address the gathering, deconstructing, and analyzing of past and simulated events to determine the risk of their occurrence, lessons learned and to identify mitigating strategies?

☐ Yes

☐ No

Q-9 Does Dr. Hnatio's dissertation address the types of information that should be collected and analyzed in order to produce mitigating strategies for adverse events?

☐ Yes

☐ No

Q-10 Does Dr. Hnatio's dissertation address the types of information that should be collected and analyzed in order to produce the actionable intelligence to intervene, i.e., the FDA uses the substitute term of "signals"?

☐ Yes

☐ No

Q-11 Does Dr. Hnatio's doctoral dissertation specifically address the need to consider all complex systems including the food supply system in a holistic fashion, i.e., the FDA uses many substitute terms such as food lifecycle, field to fork, entire food supply chain?

☐ Yes

☐ No

Q-12 Does Dr. Hnatio's doctoral dissertation specifically address the methods used to identify risks and their associated risk reduction measures, i.e., the FDA uses the substitute term "mitigating strategies"?

☐ Yes

☐ No

Q-13 Does Dr. Hnatio's doctoral dissertation present a systems model that subsumes both intentional attacks and unintentional events?

☐ Yes

☐ No

Q-14 Does Dr. Hnatio's doctoral dissertation specifically address the need to continuously monitor the behavior of complex systems such as the food supply system?

☐ Yes

☐ No

Q-15 Does Dr. Hnatio's doctoral dissertation specifically address how to make the best investments in to reduce risk and prevent incidents before they happen, i.e., the FDA uses the substitute terms "intervention" and "risk mitigation strategies"?

☐ Yes

☐ No

Q-16 Does Dr. Hnatio's doctoral dissertation specifically address the use of information technology methods including the development of operational computer software to implement a science and risk-based approach to managing risk?

☐ Yes

☐ No

Q-17 Does Dr. Hnatio's doctoral dissertation specifically address the protection of all critical infrastructures, including the food supply system, as a science that relies on science and risk based methods?

☐ Yes

☐ No

Q-18 Does Dr. Hnatio's doctoral dissertation specifically address critical nodes?

☐ Yes

☐ No

Q-19 Does Dr. Hnatio's doctoral dissertation specifically address determining best response alternatives to system emergencies?

☐ Yes

☐ No

Q-20 Does Dr. Hnatio's doctoral dissertation specifically address the use of computer automated software applications for developing operational software tools across critical infrastructures including the food and agricultural vertical?

☐ Yes

☐ No

Q-21 Did the FDA cite Dr. Hnatio's doctoral dissertation in the FDA's Food Protection Plan, the Food Defense Mitigation Strategies Database, iRisk and FREE-B tools?

☐ Yes

☐ No

Q-22 Does the FDA/HHS have any policies about copyrighting the substantive works of other scientific researchers in the absence of due diligence and without the author's permission?

☐ Yes

☐ No

Q-23 Please attach the HHS/FDA policy as it relates to government and it contractors or subcontractors copyrighting the substantial works of others without permission.

Q-24 Please attach a copy of that portion of the HHS OGC due diligence analysis that specifically addresses Dr. Hnatio's doctoral dissertation. If the HHS OGC did not conduct a due diligence analysis of Dr. Hnatio's dissertation please so signify below.

☐ The HHS OGC did not conduct a due diligence examination of Dr. Hnatio's dissertation as part of their investigation of FoodQuestTQ's allegations in this matter.

Q-25 Please attach the HHS/FDA policies as they relate to plagiarism by the FDA or its contractors and subcontractors of another scientist's research.

Q-26 Please attach a copy of the HHS/FDA or contractor or subcontractor applications for any or all copyrights for the FDA Food Protection Plan, the Food Defense Mitigation Strategies Database, Food Defense Plan Builder, iRisk and FREE-B tools.

Q-27 Please attach a copy of the FDA policy document that justifies, authorizes and guides government and government copyright of work developed using public funds.

2. The Subcommittee is investigating whether the FDA Food Protection Plan is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or other FoodQuestTQ owned intellectual property. FoodQuestTQ has shared a document with the Subcommittee that details 20 examples of their ideas that they allege are being used in the FDA produced Food Protection Plan, Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database. To assist the Subcommittee investigation, please answer the following questions pertaining to the FDA Food Protection Plan.

Q-1 Are FoodQuestTQ ideas being used in the FDA produced Food Protection Plan?

☐ Yes

☐ No

Q-2 Does the FDA Food Protection Plan address the ideas of prevention and interdiction of food events, i.e., the FDA uses the substitute term "intervention"?

☐ Yes

☐ No

Q-3 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan. Please insert the date below.

_ _ / _ _ / 20_ _

Q-4 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-5 Does the FDA Food protection Plan address the idea of indicators and warnings of impending food events, i.e., the FDA uses the substitute term "signals"?

☐ Yes

☐ No

Q-6 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan. Please insert the date below.

_ _ / _ _ / 20_ _

Q-7 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-8 Does the FDA Food Protection Plan address the idea of determining the probability of a food event happening based on the vulnerability and consequences that would result from a successful attack?

☐ Yes

☐ No

Q-9 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan. Please insert the date below.

_ _ / _ _ / 20_ _

Q-10 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-11 Does the FDA Food Protection Plan address the idea of implementing step-by-step countermeasure to address food risks, i.e., the FDA uses the substitute term “mitigating strategies”?

☐ Yes

☐ No

Q-12 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-13 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-14 Does the FDA Food Protection Plan address the idea of prioritizing areas of importance along the food supply chain and in operating food facilities based on the probability of a food event happening, i.e., the FDA uses the substitute term “high risk areas”?

☐ Yes

☐ No

Q-15 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-16 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-17 Does the FDA Food Protection Plan address the idea of gathering, deconstructing and analyzing food incidents as a method to identify high risk agents?

☐ Yes

☐ No

Q-18 Please provide the date that the above idea was first reduced to written form as part the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-19 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-20 Does the FDA Food Protection Plan address the idea of how to collect and analyze the right types of information in order to identify actionable intelligence to prevent food safety and food defense incidents?

☐ Yes

☐ No

Q-21 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-22 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-23 Does the FDA Food Protection Plan address the idea of addressing the food supply as a holistic system, i.e., the FDA uses substitute terms such as “entire supply chain”, “from field to fork” and “complete food lifecycle.”

☐ Yes

☐ No

Q-24 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-25 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-26 Does the FDA Food Protection Plan address the idea of identifying specific countermeasures to reduce the risks associated with specific food threats, i.e., the FDA uses the substitute term “mitigation strategies”?

☐ Yes

☐ No

Q-27 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-28 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-29 Does the FDA Food Protection Plan address the idea of targeting risk countermeasures to achieve the best results, i.e. the FDA uses the term “mitigation strategies”?

☐ Yes

☐ No

Q-30 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-31 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-32 Does the FDA Food Protection Plan address the idea of integrally tying the use of specific information technology applications, i.e., computer software tools, to food industry operational requirements?

☐ Yes

☐ No

Q-33 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-34 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-35 Does the FDA Food Protection Plan address the idea of using a systems model and treating food protection as a science that relies on risk-based quantitative methods for determining risk values?

☐ Yes

☐ No

Q-36 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-37 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-38 Does the FDA Food Protection Plan address the idea of combining advanced modeling, science based analysis and advanced information technology to produce operational industry software applications?

☐ Yes

☐ No

Q-39 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-40 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-41 Does the FDA Food Protection Plan address the idea of determining the best response alternatives to food related emergencies?

☐ Yes

☐ No

Q-42 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-43 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-44 Does the FDA Food Protection Plan address the idea of using automated software tools for developing science and risk-based solutions to operational risk management challenges faced by the food industry?

☐ Yes

☐ No

Q-45 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Protection Plan? Please insert the date below.

_ _ / _ _ / 20_ _

Q-46 Please attach the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-47 Please attach a complete list of the names and contact information for consultants and contractor organizations used by the FDA to develop and write the Food Protection Plan for the Subcommittee's review.

Q-48 Please attach a complete listing of the specific names and contact information for all FDA, FDA contractor employees or consultants who have received awards for the development of the FDA Food Protection Plan.

3. The Subcommittee is investigating whether the FDA Food Defense Plan Builder is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or other FoodQuestTQ owned intellectual property. FoodQuestTQ has shared a document with the Subcommittee that details 20 examples of their ideas that they allege are being used in the FDA produced Food Protection Plan, Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database. To assist the Subcommittee investigation, please answer the following questions pertaining to the FDA Food Defense Plan Builder.

Q-1 Are FoodQuestTQ ideas being used in the FDA produced Food Defense Plan Builder?

☐ Yes

☐ No

Q-2 Did members of the FDA Food Defense Team receive briefings from FoodQuestTQ describing their Food DefenseTQ (with TQ standing for threat quotient) and Food Defense Architect products?

☐ Yes

☐ No

Q-3 Does the FDA Food Defense Plan Builder include broad areas of food defense interest accompanied by carefully organized risk mitigation questions?

☐ Yes

☐ No

Q-4 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-5 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-6 Does the FDA Food Defense Plan Builder use Likert scales to quantify levels of risk?

☐ Yes

☐ No

Q-7 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-8 Does the FDA Food Defense Plan Builder use the taxonomy of identifying areas of risk and creating well organized sets of associated questions the answers to which identify security "gaps"?

☐ Yes

☐ No

Q-9 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-10 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-11 Does the FDA Food Defense Plan Builder identify risk reduction countermeasures, i.e., the FDA uses the substitute term "mitigation strategies?

☐ Yes

☐ No

Q-12 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-13 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee.

Q-14 In applying Likert values to quantify risk does the FDA consider any elements of the threat continuum model of deterrence, detection, intervention, response and mitigation?

☐ Yes

☐ No

Q-15 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-16 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-17 Does the FDA Food Defense Plan Builder integrally tie the use of information technology to the identification of risks, the quantification of risk levels and associated risk reduction countermeasures, i.e., the FDA uses the substitute term “mitigations strategies”?

☐ Yes

☐ No

Q-18 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-19 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-20 Can the FDA Food Defense Plan Builder tool be used by food companies to monitor their performance over time?

☐ Yes

☐ No

Q-21 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-22 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-23 Does the FDA Food Defense Plan Builder help food companies target the best investments they can make to mitigate risk through the use of Likert scale risk quantification?

☐ Yes

☐ No

Q-24 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-25 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-26 Does the FDA Food Defense Plan Builder integrally tie the use of information technology to food industry operational risk management challenges?

☐ Yes

☐ No

Q-27 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-28 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-29 Does the FDA Food Defense Plan Builder provide a vulnerability assessment based on the use of Likert scale quantification?

☐ Yes

☐ No

Q-30 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Plan Builder? Please insert the date below.

_ _ / _ _ / 20_ _

Q-31 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-32 Were any non-public funds used to build Food Defense Plan Builder?

☐ Yes

☐ No

Q-33 If the answer is "No" to question 5 above, please provide the Subcommittee with the specific laws that were used by the FDA to justify a government copyright of a product produced at taxpayer expense?

Q-34 Does the FDA decision to copyright automated tools produced at taxpayer expense indicate in any way the potential for the FDA to restrict their future use without government permission?

☐ Yes

☐ No

Q-35 Does the FDA intend, now or anytime in the future, to charge industry or the public any type of "user" or development fee for the right to use FDA copyrighted automated computer tools or other products?

☐ Yes

☐ No

Q-36 Did the notion of charging "user" fees for the future use of FDA developed computer tools or other services enter, in any way, into FDA's decision to copyright Food Defense Plan Builder?

☐ Yes

☐ No

Q-37 Did FDA's policy to charge the food industry "user fees" for FDA services influence, in any way the HHS OGC decision to close the OGC-HHS "investigation" of FoodQuestTQ's concerns that FDA was competing with small business?

☐ Yes

☐ No

Q-38 Was the FDA decision to copyright Food Defense Plan Builder concurred on by the FDA Chief Counsel?

☐ Yes

☐ No

Q-39 If so, please provide a copy of the above document signed or initialed by the Office of Chief Counsel FDA.

Q-40 Was the FDA decision to copyright Food Defense Plan Builder concurred on by the OGC HHS?

☐ Yes

☐ No

Q-41 If so, please provide a copy of the above document signed or initialed by the OGC HHS.

Q-42 Did the Director Office of Acquisitions and Grant Services (OAGS) concur on the FDA decision to copyright Food Defense Plan Builder?

☐ Yes

☐ No

Q-43 If so, please provide a copy of the above document signed or initialed by the Office of Acquisitions and Grant Services.

Q-44 Please provide a complete list of the names and contact information for consultants and contractor organizations used by the FDA to develop Food Defense Plan Builder for the Subcommittee's review.

Q-45 Please provide a copy of the FDA signed and dated contract with Valbrea Technolgies to develop Food Defense Plan Builder.

Q-46 Please provide a complete listing of the specific names and contact information for all FDA, FDA contractor employees or consultants who have received awards for the development of Food Defense Plan Builder.

4. The Subcommittee is investigating whether the FDA Food Defense Mitigation Strategies Database is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or other FoodQuestTQ owned intellectual property. FoodQuestTQ has shared a June 3, 2013, document with the Subcommittee that details 20 examples of their ideas that they allege are being used in the FDA produced Food Protection Plan, Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database. To assist the Subcommittee investigation, please answer the following questions pertaining to the FDA Food Defense Mitigation Strategies Database.

Q-1 Are FoodQuestTQ ideas being used in the FDA Food Defense Mitigation Strategies Database?

☐ Yes

☐ No

Q-2 Did members of the FDA Food Defense Team receive briefings from FoodQuestTQ in which the company shared their intellectual property describing the workings of their Food DefenseTQ (with TQ standing for threat quotient) and Food Defense Architect food defense plan builder tools?

☐ Yes

☐ No

Q-3 Does the FDA Food Defense Mitigation Strategies Database use the threat continuum elements of prevention and interdiction, i.e., the FDA uses the substitute term "intervention", and communication and response?

☐ Yes

☐ No

Q-4 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-5 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-6 Does the FDA Food Defense Mitigation Strategies Database use vulnerability and potential consequence in combination with Likert scales to quantify risk levels?

☐ Yes

☐ No

Q-7 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-8 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-9 Does the FDA Food Defense Mitigation Strategies Database identify risk reduction countermeasures, i.e., the FDA uses the substitute term “mitigation strategies”?

☐ Yes

☐ No

Q-10 Please provide the specific date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-11 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-12 Does the FDA Food Defense Mitigation Strategies Database use the taxonomy of identifying areas of risk and creating well organized sets of associated questions the answers to which identify security “gaps”?

☐ Yes

☐ No

Q-13 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-14 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-15 Does the FDA Food Defense Mitigation Strategies Database identify “hot spots” in operating food facilities, i.e., the FDA uses the substitute term high risk areas?

☐ Yes

☐ No

Q-16 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-17 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-18 Does the FDA Food Defense Mitigation Strategies Database address areas of food defense interest accompanied by carefully organized risk mitigation questions?

☐ Yes

☐ No

Q-19 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-20 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-21 Does the FDA Food Defense Mitigation Strategies Database address the idea of identifying specific countermeasures to reduce the risks associated with specific food threats, i.e., the FDA uses the substitute term “mitigation strategies”?

☐ Yes

☐ No

Q-22 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-23 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-24 Does the FDA Food Defense Mitigation Strategies Database address the idea of implementing step-by-step countermeasures to address food risks, i.e., the FDA uses the substitute term “mitigating strategies”?

☐ Yes

☐ No

Q-25 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-26 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-27 Does the FDA Food Defense Mitigation Strategies Database address the idea of how to collect and analyze the right types of information in order to identify actionable intelligence to prevent food safety and food defense incidents?

☐ Yes

☐ No

Q-28 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-29 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-30 Does the FDA Food Defense Mitigation Strategies Database address the idea of targeting risk countermeasures to achieve the best results, i.e. the FDA uses the term “mitigation strategies”?

☐ Yes

☐ No

Q-31 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-32 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-33 Does the FDA Food Defense Mitigation Strategies Database integrally tie the use of specific information technology applications, i.e., computer software tools, to food industry operational requirements?

☐ Yes

☐ No

Q-34 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-35 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-36 Is the FDA Food Defense Mitigation Strategies Database a computer automated software tool for providing operational risk management solutions the food industry?

☐ Yes

☐ No

Q-37 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-38 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-39 Does the FDA Food Defense Mitigation Strategies Database address the idea of "critical nodes"?

☐ Yes

☐ No

Q-40 Please provide the date that the above idea was first reduced to written form as part of the FDA Food Defense Mitigation Strategies Database? Please insert the date below.

_ _ / _ _ / 20_ _

Q-41 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-42 Please provide a complete list of the names and contact information for consultants and contractor organizations used by the FDA to develop and write the Food Defense Mitigation Strategies Database for the Subcommittee's review.

Q-43 Please provide a complete listing of the specific names and contact information for all FDA, FDA contractor employees or consultants who have received awards for the development of the FDA Food Defense Mitigation Strategies Database.

5. The Subcommittee is investigating whether the FDA iRisk computer software tool is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or other FoodQuestTQ owned intellectual property. FoodQuestTQ has shared a document with the Subcommittee that details 20 examples of their ideas that they allege are being used in the FDA produced Food Protection Plan, Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database. To assist the Subcommittee investigation, please answer the following questions pertaining to the FDA iRisk computer software tool.

Q-1 Are FoodQuestTQ ideas being used in the FDA iRisk computer software tool?

☐ Yes

☐ No

Q-2 Does the FDA iRisk computer software tool address the idea of determining the probability of a food event happening based on the vulnerability and consequences that would result from the event?

☐ Yes

☐ No

Q-3 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-4 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-5 Does the FDA iRisk computer software tool identify risk reduction countermeasures, i.e., the FDA uses the substitute term “mitigation strategies?

☐ Yes

☐ No

Q-6 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-7 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-8 Does the FDA iRisk computer software tool integrally tie the use of information technology to the identification of risks, the quantification of risk levels and associated risk reduction countermeasures, i.e., the FDA uses the substitute term “mitigations strategies”?

☐ Yes

☐ No

Q-9 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-10 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-11 Does the FDA iRisk computer software tool use the taxonomy of taking areas of risk and creating well organized sets of associated questions the answers to which identify security "gaps"?

☐ Yes

☐ No

Q-12 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-13 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-14 Does the FDA iRisk computer software tool integrally tie the use of information technology to food industry operational risk management challenges?

☐ Yes

☐ No

Q-15 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-16 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-17 Does the FDA iRisk computer software tool address the idea of how to collect and analyze the right types of information in order to identify actionable intelligence to prevent food incidents?

☐ Yes

☐ No

Q-18 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-19 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-20 Does the FDA iRisk computer software tool address the idea of prioritizing areas of importance along the food supply chain and in operating food facilities based on the probability of a food event happening, i.e., the FDA uses the substitute term “high risk areas”?

☐ Yes

☐ No

Q-21 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-22 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-23 Does the FDA iRisk computer software tool address the idea of gathering, deconstructing and analyzing food incidents as a method to identify the probability of high risk events?

☐ Yes

☐ No

Q-24 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-25 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-26 Does the FDA iRisk computer software tool address the idea of identifying and prioritizing high risk agents?

☐ Yes

☐ No

Q-27 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-28 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-29 Does the FDA iRisk computer software tool address the idea of the food supply as a holistic system, i.e., the FDA uses substitute terms such as “entire supply chain”, “from field to fork” and “complete food lifecycle.”

☐ Yes

☐ No

Q-30 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-31 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-32 Does the FDA iRisk computer software tool address the idea of implementing step-by-step countermeasures to address food risks, i.e., the FDA uses the substitute term “mitigating strategies”?

☐ Yes

☐ No

Q-33 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-34 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-35 Does the FDA iRisk computer software tool address the idea of using a systems model and treating food protection as a science that relies on risk-based quantitative methods for determining risk values?

☐ Yes

☐ No

Q-36 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-37 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-38 Does the FDA iRisk computer software tool address the idea of targeting risk countermeasures to achieve the best results, i.e. the FDA uses the term “mitigation strategies”?

☐ Yes

☐ No

Q-39 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-40 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-41 Does the FDA iRisk computer software tool address the idea of combining advanced modeling, science based analysis and advanced information technology to produce operational industry software applications?

☐ Yes

☐ No

Q-42 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-43 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-44 Does the FDA iRisk computer software tool address the idea of determining the best response alternatives to food related emergencies?

☐ Yes

☐ No

Q-45 Please provide the date that the above idea was first reduced to written form as part of the FDA iRisk computer software tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-46 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-47 Please provide a complete list of the names and contact information for consultants and contractor organizations used to develop the FDA iRisk computer software tool for the Subcommittee's review.

Q-48 Please provide a complete listing of the specific names and contact information for all FDA, FDA contractor employees or consultants who have received awards for the development of the FDA Food Defense Mitigation Strategies Database.

6. The Subcommittee is investigating whether the FDA FREE-B tool is substantially based on Dr. Hnatio's doctoral dissertation, his patent and/or other FoodQuestTQ owned intellectual property. FoodQuestTQ has shared a document with the Subcommittee that details 20 examples of their ideas that they allege are being used in the FDA produced Food Protection Plan, Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database. To assist the Subcommittee investigation, please answer the following questions pertaining to the FDA FREE-B tool.

Q-1 Are FoodQuestTQ ideas being used in the FDA FREE-B tool?

☐ Yes

☐ No

Q-2 Does the FDA FREE-B tool use simulated events, i.e., scenarios?

☐ Yes

☐ No

Q-3 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-4 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-5 Does the FDA FREE-B tool bring select groups of decision makers and technical personnel who would be involved in managing an event in the real world together to manage hypothetical simulations, i.e., scenarios, of complex events?

☐ Yes

☐ No

Q-6 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-7 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-8 Are participants in FREE-B exercises provided with the opportunity to systematically consider and plan in advance for complex contingencies?

☐ Yes

☐ No

Q-9 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-10 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-11 Do subject matter experts and decision makers, cut across both the horizontal and vertical boundaries of organizations participate in FREE-B exercises?

☐ Yes

☐ No

Q-12 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-13 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-14 Is one of the important objectives of FREE-B exercises to encourage shared situational awareness from the policy to the operational level.

☐ Yes

☐ No

Q-15 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-16 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-17 Does FREE-B use science-based simulations, i.e., of scenarios of hypothetical events and situations?

☐ Yes

☐ No

Q-18 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-19 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-20 Are aspects of these simulations, i.e., scenarios, based on real world events that have been deconstructed to use as part of exercises?

☐ Yes

☐ No

Q-21 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-22 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-23 Do FREE-B simulated exercises, i.e., scenarios, reflect the *a-priori* (i.e., before the fact) thinking of the multidisciplinary experts who develop and reverse engineer scenarios that are used for FREE-B exercises?

☐ Yes

☐ No

Q-24 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-25 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-26 Do participants in FREE-B exercises identify the decisions they would make, identify the outcomes and the extended-order effects of their decisions as they work through simulations, i.e., scenarios?

☐ Yes

☐ No

Q-27 Please provide the date that the above idea was first reduced to written form as part of the FDA FREE-B tool? Please insert the date below.

_ _ / _ _ / 20_ _

Q-28 Please provide the relevant portion of the above FDA dated document for review by the Subcommittee staff.

Q-29 Please attach a complete list of the names and contact information for consultants and contractor organizations used to develop the FDA FREE-B tool for the Subcommittee's review.

Q-30 Please attach a complete listing of the specific names and contact information for all FDA, FDA contractor employees or consultants who have received awards for the development of the FDA FREE-B tool.

C. The Subcommittee is investigating whether the FDA has retaliated against FoodQuestTQ for resisting the government's actions in this matter.

1. The Subcommittee is investigating whether the FDA action to preclude FoodQuestTQ from participating in the FDA sponsored industry workshop at GMA Headquarters to demonstrate their competing commercial product was motivated by FDA's desire to avoid commercial competition. To assist in the Subcommittee investigation, please answer the following questions.

Q-1 Was FoodQuestTQ prohibited by the FDA from attending the workshop?

☐ Yes

☐ No

Q-2 Did the FDA Office of Acquisitions and Grant Services (OAGS) approve Mr. Menikheim's decision to preclude FoodQuestTQ's participation in the FDA sponsored workshop?

☐ Yes

☐ No

Q-3 Did the Office of Acquisitions and Grant Services (OAGS) concur that FoodQuestTQ should be excluded from attending the workshop?

☐ Yes

☐ No

Q-4 Please attach for the Subcommittee's review a copy of the Office of Acquisitions and Grant Services (OAGS) concurrence to exclude FoodQuestTQ from the FDA workshop. If no one conferred with OAGS regarding the matter please so signify below.

☐ No one conferred with the Office of Acquisitions and Grant Services (OAGS) to seek concurrence on the matter.

Q-5 Please have Mr. Menikheim answer the following question for the record. Did you offer FoodQuestTQ the opportunity to participate in the workshop if they agreed not to demonstrate their own food defense plan builder tool?

☐ Yes

☐ No

Q-6 Was the FDA aware that FoodQuestTQ products are used to build food defense plans prior to the December 2012 workshop?

☐ Yes

☐ No

Q-7 Provide the date that the FDA first learned that FoodQuestTQ would be participating in the December 2012 FDA sponsored workshop to brief industry on their food defense planning tool? Please insert the date below.

_ _ / _ _ / 2012

Q-8 Please provide the date that FDA first informed the Grocery Manufacture's Association that FoodQuestTQ was prohibited from participating in the December 2012 FDA sponsored workshop. Please insert the date below.

_ _ / _ _ / 2012

Q-9 Were only food manufacturers and processors allowed to attend the workshop?

☐ Yes

☐ No

Q-10 Did Mr. George Hughes, Senior Advisor, Counterterrorism & Intelligence, FDA Office of Criminal Investigations appear in the Tyco Integrated Systems food defense promotional before or after the FDA sponsored workshop held at GMA Headquarters in December 2012?

☐ Before

☐ After

Q-11 Please insert the date that FDA participated in Tyco Integrated Systems food defense promotional below.

_ _ / _ _ / 20_ _

Q-12 Please provide a complete list of the names and affiliations of <u>all</u> participants in the December 2012 FDA workshop held at the Grocery Manufacturer's Association.

2. The Subcommittee is investigating whether the FDA action to preclude FoodQuestTQ from participating in the FDA industry workshop held at GMA Headquarters in December 2012 was in retaliation for the publication of a FoodQuestTQ article describing weaknesses in FDA's approach to vulnerability assessment and food defense. We have reviewed an article published on December 6, 2012, relating to a food vulnerability assessment tool being used and further developed by the FDA called C.A.R.V.E.R. plus Shock. To assist the Subcommittee investigation of this matter, please answer the following questions.

Q-1 Is the FDA familiar with the term "baseline threat?"

☐ Yes

☐ No

Q-2 Does the FDA have any official baseline threat against which the U.S. food supply must be protected? If so, please attach a redacted unclassified copy of the FDA's official baseline threat.

☐ Yes

☐ No

Q-3 Has the FDA officially defined the rules of engagement when confronted with a terrorist attack against the food supply? If so, please attach a redacted unclassified copy of the Agency's official policy.

☐ Yes

☐ No

Q-4 How much money has been obligated by the FDA on C.A.RV.E.R. Plus Shock from the beginning of FY 2012 to the current time? Please insert the dollar amount below.

$_ _ _ , _ _ _ , _ _ _ .00

Q-5 Did the publication of the FoodQuestTQ article raise concerns within the FDA?

☐ Yes

☐ No

Q-6 Please have Ms. Leanne Jackson of the FDA Food Defense Team answer the following question for the record. How many times did Ms. Jackson open and/or send via e-mail the December 6, 2012, FoodQuestTQ article to anyone else in the FDA or the food industry? Please insert the <u>total</u> number below.

The December 6, 2012, FoodQuestTQ article was opened and/or sent to others by Ms. Leanne Jackson, FDA, _ _ times.

Q-7 Please attach a list of all of the names, affiliations and contact information for each of the individuals Ms. Jackson contacted with respect to the December 6, 2012, FoodQuestTQ article.

Q-8 Please attach all copies of all correspondence including letters, notes and e-mails that Ms. Jackson sent or received from others in the FDA, industry or from any other source related in any way to the FoodQuestTQ article of December 6, 2012, for the Subcommittee's review.

3. The Subcommittee is investigating the FDA public appearance of Mr. George Hughes, Senior Advisor, Counterterrorism & Intelligence, FDA Office of Criminal Investigations in a Tyco Integrated Systems food defense promotional. The Subcommittee investigation has disclosed a web link showing the Tyco Integrated Systems promotional of food defense. To assist the Subcommittee's investigation, please answer the following questions.

Q-1 Does Tyco Integrated Systems produce software used by the food industry?

☐ Yes

☐ No

Q-2 Is Tyco Integrated Systems a competitor of FoodQuestTQ LLC?

☐ Yes

☐ No

Q-3 Is Tyco Integrated Systems a food processor or manufacturer?

☐ Yes

☐ No

Q-4 Was Tyco Integrated Systems allowed to attend the FDA sponsored workshop held at the Grocery Manufacturer's Association in December 2012?

☐ Yes

☐ No

Q-5 Is or has Tyco Integrated Systems ever been a contractor to the Food and Drug Administration?

☐ Yes

☐ No

Q-6 Is or has Tyco Integrated Systems ever been a contractor or subcontractor to Battelle Memorial Institute under any FDA sponsored contract?

☐ Yes

☐ No

4. The Subcommittee is investigating what the involvement of Leavitt Partners (now known as the Acheson Group) was in the matter of FoodQuestTQ. To assist the Subcommittee, please answer the following questions.

Q-1 Is Leavitt Partners a food processor or manufacturer?

☐ Yes

☐ No

Q-2 Was Leavitt Partners allowed to attend the FDA sponsored workshop held at the Grocery Manufacturer's Association in December 2012?

☐ Yes

☐ No

Q-3 Please provide a comprehensive list of all private sector companies involved in any aspect of food safety and food defense that have received public endorsements by the FDA.

Q-4 Is or has Leavitt Partners or the Acheson Group ever been a contractor to the Food and Drug Administration?

☐ Yes

☐ No

Q-5 Is or has Leavitt Partners or the Acheson Group ever been a contractor or subcontractor to Battelle Memorial Institute under any FDA sponsored contract?

☐ Yes

☐ No

Q-6 Was Dr. Jennifer McEntire under contract to the FDA or any FDA subcontractor involved in the development of Food Defense Plan Builder?

☐ Yes

☐ No

Q-6 Was Dr. Jennifer McEntire under contract to the FDA or any FDA subcontractor involved in the development of the FREE-B tool?

☐ Yes

☐ No

Q-7 Was Dr. Jennifer McEntire under contract to the FDA or any FDA subcontractor involved in the development of the Food Defense Mitigation Strategies Database tool?

☐ Yes

☐ No

Q-8 Did Dr. Jennifer McEntire provide the FDA with FoodQuestTQ proprietary information during the development of the FDA Food Defense Plan Builder, the FREE-B tools and/or the Food Defense Mitigation Strategies Database?

☐ Yes

☐ No

☐ Do not know

Q-9 Was Dr. David Acheson ever an employee of the FDA? If so, please provide the dates of employment and the positions he occupied. If so, also please include the specific dates that he may have served as the interim Director of CFSAN.

☐ Yes

☐ No

Q-10 Has Dr. Acheson or other employees of the Acheson Group been or are currently under contract to the FDA or any FDA subcontractor.

☐ Yes

☐ No

Q-11 If so, does the nature of the work involve food policy, safety, food defense and/or food risk management activities. If "yes", please specify the activities and the nature of the contract.

☐ Yes

☐ No

5. The Subcommittee is investigating whether the FDA "blacklisted" and/or FDA employees engaged in any forms of defamation involving FoodQuestTQ. To assist the Subcommittee investigation, please answer the following questions.

Q-1 Has any employee of the FDA discussed with anyone in private industry any aspect of the dispute between the FDA and FoodQuestTQ?

☐ Yes

☐ No

Q-2 Has any employee of HHS discussed with anyone in private industry any aspect of the dispute between the FDA and FoodQuestTQ?

☐ Yes

☐ No

Q-3 Did any FDA/HHS employee discuss any aspect of the FoodQuestTQ matter with Drs. David Acheson or Jennifer McIntyre of Leavitt Partners (now known as the Acheson Group)?

☐ Yes

☐ No

Q-4 Is the FDA aware that Dr. Acheson terminated his business relationship with FoodQuestTQ immediately after he was interviewed by HHS and FDA officials.

☐ Yes

☐ No

Q-5 Please attach a list of the names and contact information for all HHS and FDA employees who held discussions, traded e-mails or had other communications with industry regarding the dispute between the FDA and FoodQuestTQ?

Q-6 Please provide copies of any notes, memos, letters or other correspondence/ communications, including e-mails, with industry or other government agencies regarding the FoodQuestTQ matter.

D. The Subcommittee is investigating the role played by the FDA Office of Acquisitions and Grants Services (OAGS) in the FoodQuestTQ matter. To assist the Subcommittee investigation, please answer the following questions.

Q-1 Do federal procurement and acquisition rules require that the FDA and HHS consider the consequences of going into competition with small businesses?

☐ Yes

☐ No

Q-2 Do federal procurement and acquisition rules require FDA cost comparisons based on the availability of the same or similar products from industry?

☐ Yes

☐ No

Q-3 Was the FDA Office of Acquisitions and Grants Services (OAGS) FDA aware that similar products to the FDA produced Food Defense Plan Builder, iRisk, FREE-B and the Risk Mitigation Strategies Database were already developed and being commercially sold by small businesses including FoodQuestTQ?

☐ Yes

☐ No

Q-4 Does the FDA Office of Acquisitions and Grants Services (OAGS) concur with the April 26, 2013, HHS OGC legal opinion stating that there is no relationship between the Federal Activities Inventory (FAIR) Act [P.L. 105-270], the implementing provisions of Office of Management and Budget (OMB) Circular A-76, and the Federal Acquisition Regulations (FAR) and the FoodQuestTQ matter?

☐ Yes

☐ No

Q-5 Does the FDA Office of Acquisitions and Grants Services (OAGS) adhere to the Office of Management and Budget (OMB) and office of Government Ethics (OGE) rules and guidelines with respect to the utilization of services from the private sector?

☐ Yes

☐ No

Q-6 Does the FDA Office of Acquisitions and Grants Services (OAGS) consider the development of food risk management software an inherently government function?

☐ Yes

☐ No

Q-7 Did the FDA Office of Acquisitions and Grants Services (OAGS) conduct the due diligence required under OMB and OGE rules and guidance in their contract dealings with Battelle Memorial Institute?

☐ Yes

☐ No

Q-8 In conducting The Agency's due diligence of the Battelle Memorial Institute contract did the FDA determine that the capability to build computer automated food risk management tools was widely available from the private sector at dramatically reduced cost to the taxpayer?

☐ Yes

☐ No

Q-9 Please attach a copy of the dated, signed and/or initialed FDA due diligence determination for review by the Subcommittee.

Q-10 Please attach a list of the names and full contact information for the FDA's contract officer (CO) and his/her contracting officer's technical representative (COTR) who oversee the FDA's contract dealings with Battelle Memorial Institute, the Institute for Food Technologists, Leavitt Partners (now known as the Acheson Group), Tyco Integrated Systems, the Institute for Food Technologists and Vabrea Technologies.

Q-11 Do the FAIR Act and OMB Circular A-76 call for the conduct of realistic and fair cost comparisons before a federal agency makes a determination to build non-inherently governmental products in house?

☐ Yes

☐ No

Q-12 Please attach the FDA policies and procedures that are used to assure that realistic and fair cost determinations are being made by HHS/FDA prior to the procurement of non-inherently governmental products including determination for the in house development

of computer software. Please highlight the pertinent provisions requiring realistic and fair cost determinations in cases like the FoodQuestTQ matter.

Q-13 Does the FDA Office of Acquisitions and Grants Services (OAGS) currently procure computer development and support work from small businesses?

☐ Yes

☐ No

Q-14 Does the FDA Office of Acquisitions and Grants Services (OAGS) have mechanisms to conduct "sole source" procurements when a small company owns intellectual property that the Agency considers essential to its mission?

☐ Yes

☐ No

Q-15 Did the FDA Office of Acquisitions and Grants Services (OAGS) HHS/FDA ever request a "sole source" proposal from FoodQuestTQ to use their intellectual property in furtherance of the FDA's critical food safety, defense and risk management mission?

☐ Yes

☐ No

Q-16 Does the FDA Office of Acquisitions and Grants Services (OAGS) agree with the guiding principles of the Federal Acquisition Regulations (FARs), the Office of Management and Budget and the Office of Government Ethics to use commercial products and services whenever possible to save and maximize the use of taxpayer dollars?

☐ Yes

☐ No

Q-17 Does the FDA Office of Acquisitions and Grants Services (OAGS) maintain awareness of the capabilities of the commercial marketplace to save and maximize the use of taxpayer dollars?

☐ Yes

☐ No

Q-18 Does the FDA Office of Acquisitions and Grants Services (OAGS) conduct the people's business with integrity, fairness, and openness?

☐ Yes

☐ No

Q-19 Does the FDA Office of Acquisitions and Grants Services (OAGS) believe that maintaining the public's trust is an essential consideration in every aspect of the FARs system?

☐ Yes

☐ No

Q-20 Please attach a copy of the dated, signed/initialed FDA contract modification authorizing Battelle Memorial Institute and other contractors to build, maintain and modify the FDA Food Defense Plan Builder tool, the Mitigation Strategies Database, iRisk and FREE-B.

Q-21 Did the FDA Office of Acquisitions and Grants Services (OAGS) approve the "pass through" contract to Vabrea Technologies to develop Food Defense Plan Builder?

☐ Yes

☐ No

Q-22 Please attach HHS/FDA policies with respect to the use of "pass through" contracts to sidestep open and fair competition for government services.

Q-23 Please attach the FDA Office of Acquisitions and Grants Services (OAGS) concurrence copy of the Vabrea contract/subcontract.

Q-24 Please provide the <u>total</u> amount of taxpayer dollars expended to build and maintain to the current time the FDA Food Defense Plan Builder? Please insert the total amount below.

$_ _ _ , _ _ _ , _ _ _ .00

Q-25 Please provide the <u>total</u> amount of taxpayer dollars expended to build and maintain to the current time the FDA Food Defense Mitigation Strategies Database? Please insert the total amount below.

$_ _ _ , _ _ _ , _ _ _ .00

Q-26 Please provide the total amount of taxpayer dollars expended to build and maintain to the current time the iRisk? Please insert the total amount below.

$_ _ _ , _ _ _ , _ _ _ .00

Q-27 Please provide the total amount of taxpayer dollars expended to build and maintain to the current time the FREE-B tool? Please insert the total amount below.

$_ _ _ , _ _ _ , _ _ _ .00

E. The Subcommittee is investigating the role played by the FDA and HHS Offices of Small Business and Disadvantaged Utilization (OSBDU) in the FoodQuestTQ matter. To assist the Subcommittee in conducting their investigation, please answer the following questions.

Q-1 Is the FDA OSBDU mission to make special efforts to assure maximum participation by small and disadvantaged businesses in the procurement of materials and services by the FDA?

☐ Yes

☐ No

Q-2 Did the FDA Food Defense Team consult with the FDA OSBDU before they decided to build Food Defense Plan Builder?

☐ Yes

☐ No

Q-3 Did the FDA Food Defense Team consult with the FDA OSBDU before they decided to build the Food Defense Mitigation Strategies Database?

☐ Yes

☐ No

Q-4 Did the FDA Food Defense Team and/or other FDA operational units consult with the FDA OSBDU before they decided to build the iRisk computer software tool?

☐ Yes

☐ No

Q-5 Did the FDA Food Defense Team and/or other FDA operational units consult with the FDA OSBDU before they decided to build the FDA FREE-B tool?

☐ Yes

☐ No

Q-6 Was the FDA OSBDU contacted by the OGC HHS during their investigation of the FoodQuestTQ matter?

☐ Yes

☐ No

Q-7 Was the FDA OSBDU asked by OGC HHS to concur on their decision to close the FoodQuestTQ matter?

Q-8 Did the FDA OSBDU, in fact, concur on the April 26, 2013, OGC HHS letter to FoodQuestTQ?

☐ Yes

☐ No

Q-9 If so, please provide the Subcommittee with a dated, signed or initialed FDA OSBDU concurrence copy.

Q-10 When did the FDA OSBDU first become aware of the dispute between FDA and FoodQuestTQ? Please insert the date below.

_ _ / _ _ / 20_ _

Q-11 Did the FDA OSBDU reach out to FoodQuestTQ?

☐ Yes

☐ No

Q-12 If so, please insert the date the FDA OSBDU contacted FoodQuestTQ below.

_ _ / _ _ / 20_ _

Q-13 If so, please attach a copy of the FDA OSBDU correspondence sent to FoodQuestTQ.

Q-14 Was the HHS OSBDU contacted by the OGC HHS during their investigation of the FoodQuestTQ matter?

☐ Yes

☐ No

Q-15 Was the HHS OSBDU asked by OGC HHS to concur on their decision to close the FoodQuestTQ matter?

☐ Yes

☐ No

Q-16 Did the HHS OSBDU, in fact, concur on the April 26, 2013, OGC HHS letter to FoodQuestTQ?

☐ Yes

☐ No

Q-17 If so, please provide the Subcommittee with a dated, signed or initialed HHS OSBDU concurrence copy.

Q-18 When did the HHS OSBDU first become aware of the dispute between FDA and FoodQuestTQ? Please insert the date below.

_ _ / _ _ / 20_ _

Q-19 Did the HHS OSBDU reach out to FoodQuestTQ?

☐ Yes

☐ No

Q-20 If so, please insert the date the HHS OSBDU contacted FoodQuestTQ below.

_ _ / _ _ / 20_ _

Q-21 If so, please attach a copy of the HHS OSBDU correspondence sent to FoodQuestTQ.

F. The Subcommittee is investigating the role played by the National Ombudsman for Small Business of the Small Business Administration in the FDA'HHS actions in the FoodQuestTQ matter. To assist the Subcommittee investigation, please answer the following questions.

Q-1 Did the OGC HHS ever confer with the Office of the National Ombudsman for Small Business on the propriety of the federal government competing directly with small businesses like FoodQuestTQ on procurement activities that do not involve inherently governmental functions?

☐ Yes

☐ No

Q-2 Please attach a list that details by date, person and subject matter all interactions between HHS, FDA and other government officials relating in any way to the FoodQuestTQ matter including all correspondence, e-mails and telephone calls. The Subcommittee is particularly interested in discussions/interactions at the senior levels of the HHS, FDA, the Office of Government Ethics, the Office of Management and Budget and the Office of the National Ombudsman for Small Business.

Q-3 Did OGC HHS seek the concurrence of the Office of the National Ombudsman for Small Business on their April 26, 2013, letter to FoodQuestTQ?

☐ Yes

☐ No

Q-4 If so, please attach for the Subcommittee's review a dated, signed or initialed copy showing the concurrence of the National Ombudsman for Small Business on the OGC HHS decision to close the investigation of the FoodQuestTQ matter.

G. The Subcommittee is investigating whether the FDA has unfairly competed with FoodQuestTQ. The SUBCOMMITTEE is particularly interested in HHS and FDA justifications for competing directly with small business using the FoodQuestTQ matter as a case study.

Q-1 Does the FDA believe that government competition with small business is in the national interest?

☐ Yes

☐ No

Q-1 Does the HHS believe that government competition with small business is in the national interest?

☐ Yes

☐ No

Q-2 Do small businesses like FoodQuestTQ produce approximately 67 percent of the net new jobs created by our economy every year?

☐ Yes

☐ No

Q-3 Do small businesses like FoodQuestTQ make up approximately 99.7 percent of U.S. employer firms?

☐ Yes

☐ No

Q-4 Is it true that small businesses employ approximately 39 percent of high-tech workers such as scientists; engineers; and information technology workers that generate the majority of innovations that come from U.S. companies?

☐ Yes

☐ No

Q-5 Is it true that small businesses produce 13 to 14 times more patents per employee than do large firms?

☐ Yes

☐ No

Q-6 Is it true that small businesses' patents are twice as likely as those from the larger firms to be among the 1 percent most cited (that is; the most significant)?

☐ Yes

☐ No

Q-7 Do HHS/FDA agree that small businesses in America play a crucial role in creating the new jobs necessary to drive down unemployment rates?

☐ Yes

☐ No

Q-8 Do HHS/FDA agree that small businesses in America play a crucial role in keeping the nation at the cutting edge of technology innovation?

☐ Yes

☐ No

Q-9 Please attach for the Subcommittee's review the HHS-FDA policy that allows the Agency to directly compete with small food risk management businesses such as FoodQuestTQ.

☐ Yes

☐ No