Date: March 14, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: Suggested Changes to FDA Non-disclosure Agreement (NDA)

Hi Ariel:

We have completed a review of the FDA proposed NDA and it is acceptable to FQTQ with the following four modifications.

1. The "Purpose" of the agreement requires expansion to cover all three of the inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered as part of any good faith FDA review of this matter, namely:

    a. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;
    b. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, and;
    c. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

2. The "Purpose" of the agreement must indicate a fair and reasonable *quid pro quo* in the sharing of information between the two parties. If FQTQ provides the FDA with information regarding their tools for FDA evaluation then why does not the FDA share information with FQTQ regarding the FDA tools under suspicion for further evidence of theft of trade secrets and intellectual property and potential infringement in Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2?

    In addition, the agreement must reflect that the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2, is a business process and a data transformation patent. This is necessary since the guiding FDA national process document for food safety and food defense, *The FDA Food Protection Plan*, seriously infringes on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in addition to the other FQTQ tools duplicated by the FDA.

    Thus, we further suggest that the "Purpose" of the agreement be modified to explicitly state that the "parties" are engaged in a good faith review of the three allegations (as identified in 1. a.-c., above) and in so doing, must share information regarding the following FoodQuestTQ LLC food safety and food defense commercially developed tools, namely, Food SafetyTQ, Food

Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

3. The definition of "Confidential Information" requires expansion to identify the FDA national policy document and FDA tools and any FQTQ patent information and tools that must be evaluated in order to conduct a good faith review of the three allegations (as identified in 1. a.-c., above). This list currently includes Food SafetyTQ, Food Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

4. The term "Exemptions" has been defined in the standard FDA non-disclosure agreement but the term does not appear anywhere in the body of the document. This is a bit odd. In any event, the existing language, if it is to be included, requires modification by inserting the word "legally" in the verbiage as follows: "…(i) the Receiving Party or any of its Affiliates **legally** [emphasis added] possessed before the Disclosing Party or its Affiliates disclosed it under this agreement;…"

   This change is necessary because we are dealing with FQTQ "Confidential Information" i.e., trade secrets and intellectual property, that have already been taken by the FDA and are now being publicly disclosed by the FDA without FQTQ permission.

We recognize how busy you are and appreciate all of your hard efforts on our behalf. If it would be at all easier for you or save you time, we would be happy to make the above changes in the NDA and return the document to you for Ms. Dickinson's signature. All that we would require is that you e-mail to me a "soft copy" of the document in *Word* format. We will be sure to use "track changes" so that you can clearly see any modifications we make to your original document. Just let me know.

In any event, as soon as we receive the modified document we will immediately sign it and return it to you. Please call me at 240-439-4476 x-11 if you have any questions that I can help you with. Thank-you.