PHS Appeal No.: 14-0148-AA
FDA Case No.: 2013-9531

John H. Hnatio, EdD, PhD
FoodQuestTQ, LLC
7420 Hayward Drive, Suite 102
Frederick, MD 21702

JUN 30 2014

Dear Dr. Hnatio:

This letter is in response to your Freedom of Information Act (FOIA) appeal submitted on January 18, 2014, regarding your November 29, 2013, FOIA request, respectively, to the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) on behalf of FoodQuestTQ, LLC ("FoodQuestTQ"). In your appeal, you challenge FDA's search for records regarding your request for a list of companies using software that duplicates FoodQuestTQ. You specifically requested "all names of companies that have signed up on the FDA website to use the following FDA computer software tools…: 1. iRisk; 2. Food Defense Mitigation Strategies Database; 3. Food Defense Plan Builder; 4. FREE-B; and 5. CARVER + Shock."

When a requester challenges the adequacy of an agency's search, the agency must then show that it has put forth a search reasonably calculated to locate all relevant records. The standard of reasonableness which we apply to agency search procedures does not require absolute exhaustion of the files; instead, it requires a search reasonably calculated to uncover all relevant records.

Upon receipt of the appeal I asked FDA to provide an explanation as to why no records were located. FDA explained that you requested records identifying "companies that have signed up… to use" the five listed FDA food defense programs. FDA/CFSAN is committed to improving the safety and security of the food and cosmetic supply. FDA has made available food defense tools which allow companies to conduct vulnerability assessments, and determine suitable mitigation approaches. Additionally, FDA has developed several tools for the food industry to help protect our nation's food supply from deliberate acts of contamination or tampering. These programs are available to the public free of charge.

1. Food Defense Mitigation Strategies Database

FDA makes the "Food Defense Mitigation Strategies Database" (software tool #2 in your list) available to the public.[1] The tool is located at the URL and may be used without any

[1] at: http://www.accessdata.fda.gov/scripts/fooddefensemitigationstrategies/

downloading step. FDA does not require any kind of "sign up" to use this tool and therefore does not know who is using it, and has no responsive documents relevant to this tool.

2. FREE-B

FDA makes the "FREE-B" tool (software tool #4 in your list) available to the public.[2] The tool must be downloaded by users but FDA does not require a "sign up" to download the tool. FDA does provide a separate link at which interested persons may "[r]egister to receive updates and other news on FREE-B", but this is not a "sign up" to use the FREE-B tool. The fact that a business may have signed up for updates or news does not indicate that the business downloaded the tool, and businesses that have downloaded the tool were not required to provide any contact information. Therefore, any information FDA may have collected through the separate "[r]egister to receive updates and other news on FREE-B" link is not responsive to your request.

3. Food Defense Plan Builder

FDA makes the "Food Defense Plan Builder" (software tool #3 in your list) available to the public.[3] In your appeal letter, you provided a snapshot from FDA's website as support for your expectation that FDA has the information you requested with respect to the Food Defense Plan Builder – namely, "companies that have signed up on the FDA website to use the [Food Defense Plan Builder]." The web form you provided appears after a user clicks the "download" link at the URL. However, this form explicitly states that those providing information are doing so "to receive updates and news on FDA's Food Defense Plan Builder Tool," and not for the purpose of signing up to use (download) the tool. In addition, the form notes that "[p]roviding your information is not required to download the tool. All fields below are optional." The fact that a business may have signed up for updates or news does not indicate that the business downloaded the tool, and businesses that have downloaded the tool were not required to provide any contact information. Therefore, any data that may have been collected from the form you reference in your appeal is not responsive to your request.

4. CARVER + Shock (Vulnerability Assessment Software)

FDA makes the "Vulnerability Assessment Software" tool (also known as "CARVER + Shock, software tool #5 in your list) available to the public.[4] When a user clicks either the "Download Manufacturing Software" or the "Download Agriculture Software" link on this page, a web form appears entitled "Requestor Information".[5] Both the manufacturing and agriculture web forms include various fields to collect information, including a field seeking requestors' "firm name." At the bottom of each page there is a link titled "Proceed to Download". Like the web form associated with the Food Defense Plan Builder discussed above, the fields on these web forms are optional and need not be completed to download the tools. However, unlike the form for

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[2] at http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295903.htm
[3] at: http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm
[4] at: http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295900.htm
[5] See http://www.accessdata.fda.gov/scripts/email/CFSAN/reg_feedback/carverdl.cfm and http://www.accessdata.fda.gov/scripts/email/CFSAN/reg_feedback/carverag.cfm, respectively.

Food Defense Plan Builder, the forms for the Vulnerability Assessment Software tools do not indicate that they are only for news and updates on the tools, and their placement in the pathway users must follow to download the tools suggests that they are in fact "sign up" forms to use the tool. Therefore, FDA will consider the records collected through these web forms, when they include information in the "firm name" field, responsive to your request. FDA estimates that there are approximately 10,000 separate responsive records that would need to be reviewed and redacted of non-responsive and/or personal privacy information before they can be produced. Accordingly, I am requesting that FDA contact you separately regarding any fees associated with your request.

5. FDA-iRisk

The "FDA-iRisk" tool (software tool #1 in your list) is available to the public.[6] Note that this is not a page on the FDA website. There are pages on the FDA website that link to the iRisk site[7], but the tool itself, and its associated data and records, are hosted by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and not by FDA. JIFSAN was established pursuant to a cooperative agreement between FDA and the University of Maryland (UM) in April 1996 and is a jointly administered multidisciplinary research, education and outreach program. Specifically, records related to the iRisk program hosted by JIFSAN are in possession of JIFSAN's contractor, Risk Sciences International (RSI). While users must create an account to use iRisk, and the registration form collects information including "organization," the records containing information collected via the registration form are not "agency records" for the purposes of FOIA.

To qualify as an 'agency record' subject to FOIA disclosure rules, the agency must either create or obtain the requested materials, and the agency must be in control of them at the time the FOIA request is made. [8] RSI has received funding supporting the iRisk platform. However, RSI created the fields that collect information on its own, with little direction from FDA. Moreover, the records are in RSI's possession and FDA has not reviewed them. Considering these circumstances, the iRisk registration records in RSI's possession are not likely to be "agency records" for purposes of the FOIA, such that FDA reasonably concluded that it has no records responsive to the request related to iRisk.

Therefore, based on the information provided I am satisfied that FDA conducted an adequate search for responsive records with respect to 4 of the 5 software tools identified in your request. With respect to the Vulnerability Assessment Software tools ("CARVER + Shock"), FDA has located responsive records and will contact you separately regarding the fees associated with the redaction and production of these documents.

The 2007 FOIA amendments created the Office of Government Information Services (OGIS) to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a

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[6] at: https://irisk.foodrisk.org/

[7] see, e.g., http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ ; http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM316705.pdf

[8] See *Burka v. HHS*, 87 F.3d 508, 515 (D.C. Cir. 1996) (quoting *Dep't of Justice v. Tax Analysts*, 492 U.S. 136, 144 (1989)).

non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov ; or, via U.S. Mail at: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road – OGIS, College Park, MD 20740.

This letter constitutes the final decision of the Department in the matters raised specifically in this appeal. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside, or your principal place of business, or in which the agency records are located, or the District of Columbia.

Sincerely,

William H. Hall
Director, News Division
Office of the Assistant Secretary
for Public Affairs