

Via E-mail and Facsimile



Freedom of Information Office
Cohen Building
Suite 1062
Department of Health and Human Services
330 Independence Avenue SW
Washington, D.C. 20001

March 5, 2014

REF: Reports of Gross Fraud Waste and Abuse at the Food and Drug Administration and the Department of Health and Human Services

On March 4, 2014, we called the Inspector General hotline and spoke with a young lady named Avery (NLN provided). When we inquired as to the status of our reports of the gross fraud waste and abuse taking place within the Food and Drug Administration and the Department of Health and Human Services she advised us that the only possible way to obtain any information on the matter was by writing to your office.

We are a small company 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 our intellectual property without permission, 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.

On November 13, 2014, we were provided with a document by the National Ombudsman for Small Business at the Small Business Administration showing that the Department of Health and Human Services and the Food and Drug Administration are also “blacklisting” our small company in retaliation for resisting the actions being taken against us by the federal government.

In that same letter, the National Ombudsman for Small Business requested that Mr. Levinson investigate the matter. In subsequent correspondence, we have provided Mr. Levinson significant information describing the gross fraud, waste and abuse taking place within the Food and Drug Administration and the Department of Health and Human Services in order to assist any investigation he may decide to undertake.

A table of the specific information we have provided to Mr. Levinson describing the alleged misconduct, including potential violations of criminal law, appears below for your reference.

Date of Transmittal	Subject	Summary of Content
2/27/2014	Request for FTC Review of Anticompetitive Conduct by "Commercial Entities" within the Federal Government	Letter to Edith Ramirez FTC filing a complaint against the HHS, FDA and their contracted agents for alleged predatory and anticompetitive conduct

Date of Transmittal	Subject	Summary of Content
2/26/2014	Freedom of Information Act Request: In the matter of FoodQuestTQ LLC	Requests FDA confirmation of a January 19, 2014, FOIA request that has been ignored by the HHS and the FDA; no response from FDA
2/25/2014	Industry Notification re: Sherman Anti-trust, Clayton and Federal Trade Commission Acts and the Anticompetitive Conduct of the Food and Drug Administration	Notification to the food industry that unauthorized use of FoodQuestTQ LLC intellectual property in collusion with the Food and Drug Administration and the Department of Health and Human Services will be considered as predatory and anticompetitive conduct
2/23/2014	Request for a Policy Review by the FTC of Government Anticompetitive Conduct	Request that the Office of Policy Evaluation, FTC, conduct an investigation of the predatory and anticompetitive conduct of the FDA, HHS and their contracted agents in the case of FoodQuestTQ
2/22/2014	FoodQuestTQ LLC versus the Department of Health and Human Services and the Food and Drug Administration	Forwards an information memorandum to the food industry re: possible collusion between major food companies and the FDA and HHS to engage in predatory and anticompetitive conduct
2/15/2014	FQTTQ Media Policy	Responds to the criticism of congressional staff with respect to FoodQuestTQ LLC's transparency in sharing information with the media
	FOIA Appeals	Files two appeals to FOIA requests denied by HHS and FDA
1/28/2014	Senator Mikulski's Response to our Request for a Referral of our Case to Senate Judiciary Committee	Responds to the complaints of a congressional staff member that Senator Mikulski is not withholding assistance to FoodQuestTQ based on the large footprint of FDA in Maryland
	Most Recent Update for Industry on the Matter of FoodQuestTQ and the Food and Drug Administration	FoodQuestTQ information memorandum to the food industry outlining the various laws and statutes that are allegedly being violated by the FDA and HHS
1/27/2014	FOIA APPEAL Case No. 2014-92	Appeal to FDA monetary charges for processing FOIA requests that FoodQuestTQ cannot afford
1/26/2014	Violations of FOIA Law to Obstruct Justice by the Department of Health and Human Services and the Food and Drug Administration	Forwards a letter to Representative Delaney and Wittman regarding FDA and HHS violations of the FOIA
1/19/2014	FOIA Appeal: CFSAN-FDA Control No: F13-9531	Appealing FDA's resistance and use of deception to prevent the discovery and release of documents
	Second FOIA REQUEST on 1-19-2014	Requests information on employee awards for stealing FoodQuestTQ intellectual property and for duplicating the company's products
	FOIA REQUEST: RE: Matter of FoodQuestTQ vs. the Food and Drug Administration	Provides a copy of "yes" and "no" questions for response by HHS and FDA; FDA does not respond

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1/18/2014	FOIA APPEAL No. 14-00048AA; FDA Case No. 2013-7493 and Control No. F13-9531	Appealing FDA's resistance and use of deception to prevent the discovery and release of documents
	FOIA APPEAL No. 14-00048AA; FDA Case No. 2013-7493 and Control No. F13-9531	Reports the specter of deception by the HHS and the FDA in responding to legitimate FOIA requests
	FOIA APPEAL Case No. 2014-0469 WW	Expresses concern that subordinate levels of the FOIA hierarchy in FDA and HHS may be engaging in attempts to cover-up serious fraud, waste and abuse
1/15/2014	Materials relating to SBA referral for investigation of FoodQuestTQ matter	Letter to IG Levinson with "yes" and "no" questions to guide an investigation of gross fraud, waste and abuse at HHS and FDA
1/7/2014	FoodQuestTQ and FOIA Con. No. FDA1408702	Request for internal e-mails that may show "blacklisting" of FoodQuestTQ by FDA and HHS employees; FDA does not answer appeal
1/6/2014	Your letter of 11-19	Letter to Ms. Park at the General Services Administration to further explain her opinion that the FDA and HHS are in violation of federal government procurement regulations; no response
12/31/2013	Additional FoodQuestTQ background	Provides a link to a You Tube presentation giving an overview of the FoodQuestTQ case
	FOIA Appeal	Appeals the attempt by FDA and HHS employees to use deception to intentionally avoid the release of requested documents
	Request for Help	Letter to Senator Leahy requesting the help of the Senate Judiciary Committee
	FOIA Appeal	E-mail to HHS asking why appeals are not being acted upon as required by law
12/30/2013	Request for a Referral	Letter to Senator Mikulski requesting a referral to the Senate Judiciary Committee
12/22/2013	Information Memorandum to the Food Industry	Information Memorandum provides an update on media, FOIA and other activities
11/27/2013	11-27-2013 Information Memorandum to the Food Industry FINAL	Information Memorandum cautions industry against using FoodQuestTQ LLC intellectual property pirated by the FDA and HHS
11/26/2013	FoodQuestTQ Appeal: F13-7493	Reports the attempt by FDA and HHS to use deception in order to avoid the release of documents requested under the FOIA
11/22/2013	FDA Smoking Gun on the Blacklisting of FoodQuestTQ	Provided IG Levinson with an FDA-HHS memorandum provided by the National Ombudsman for Small Business as evidence of FDA blacklisting of FoodQuestTQ

Table 1: Documents and Information Provided to the OIG-HHS from 11/22/2013 to the Current Time

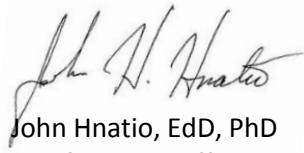
The above information raises very serious questions regarding potential violations of internal agency procedures and processes and matters of law and statute by both the Food and Drug Administration and the Department of Health and Human Services. Among these include: 1) the illegal conduct of an investigation involving allegations of criminal conduct by an attorney in the Office of General Counsel HHS; 2) obstruction of justice by numerous HHS and FDA employees; 3) repeated violations of the Freedom of Information Act in order to prevent the discovery and release of requested documents; 4) numerous violations of Title 18 U.S.C.; 5) illegal lobbying of the Congress by FDA and HHS employees; 5) the commandeering of privately owned intellectual property in the absence of due process; 6) predatory and anticompetitive conduct by the Department of Health and Human Services, the Food and Drug Administration and government contracted and regulated companies; 6) violations of internal agency and federal government policies, procurement regulations and procurement integrity processes, procedures and laws. This list is not intended to be all-inclusive and the potential exists that FDA and HHS employees have violated other processes, procedures, policies, regulations, laws and statutes in their handling of the FoodQuestTQ LLC matter.

We have also filed official complaints with both the Federal Trade Commission and the Antitrust Division of the Department of Justice describing the predatory and anticompetitive conduct of the Department of Health and Human Services, the Food and Drug Administration and government contracted universities, companies and regulated companies.

Based on the above information, we respectfully request to know whether Inspector General Levinson is in receipt of the above information and aware of the serious allegations of fraud, waste and abuse that we have been reporting over the past several months. We also request to know if Inspector General Levinson will investigate the serious matters we have brought to his attention. The Inspector General's decision is very relevant to our situation at this time as we consider our alternatives to achieve justice in this matter.

If you have any questions or require any additional information please do not hesitate to contact me directly. We look forward to hearing from you.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Hnatio".

John Hnatio, EdD, PhD
Chief Science Officer

cc:

Edith Ramirez, FTC
William Baer, DOJ
Dan Levinson, OIG-HHS