



DEPARTMENT OF HEALTH & HUMAN SERVICES

#44

Food and Drug Administration
Silver Spring, MD 20993-0002

April 8, 2014

VIA UPS

Food Quest LLC
John H. Hnatio Ed PhD
7420 Hayward Drive
Suite 102 Frederick, MD 21702 USA

Re: Letter dated January 19, 2014

Dear Dr. Hnatio:

I am writing in regards to your 66-page letter dated January 19, 2014. In correspondence dated March 10, 2014, Sarah Kotler, Deputy Director, Division of Freedom of Information, notified you that your letter was forwarded to CFSAN for review and response as general correspondence. Upon review, and in consultation with the FDA's Office of Chief Council, we have determined that your 66-page letter is comprised partly of questions which can be interpreted as requests for records under the Freedom of Information Act (FOIA) (5 U.S.C. §552) to which we intend to reply in accordance with the agency's procedure for responding to such requests. Your letter is also comprised of questions which cannot be considered as requests for records and thus, cannot be considered to be FOIA requests. See e.g., *Rodriguez- Cervantes v. HHS*, 853 F. Supp. 2d 114, 116- 17 (D.D.C. 2012) (Stating that because "[plaintiff's] letters merely pose questions . . . or ask for assistance in applying for Social Security benefits, they do not constitute valid FOIA requests."). However, FDA may consider a communication containing such questions to be general correspondence.

Those questions to which we intend to respond as FOIA requests have been referred to FDA's Division of Freedom of Information for processing and have been logged as a FOIA request (FDA FOIA control number 2014-2328).

The remaining questions, which FDA is considering to be general correspondence, will not be specifically replied to by the CFSAN. The issues raised in these questions have already been

considered and responded to through the letter and exhibits sent to you on April 26, 2013 by Mr. Dale Berkley, Department of Health and Human Services, Office of General Counsel. We consider that letter to be FDA's complete response to your communications regarding the Food Defense Plan Builder and similar software products created by FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Menikheim". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jody Menikheim

Director, Food Defense and Emergency Coordination Staff
Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition
Food and Drug Administration