Lumigenix™

www.lumigenix.com

June 8th, 2011

James L. Woods
Deputy Director, Patient Safety and Product Quality
Office of In Vitro Diagnostic Device Evaluation and Safety
10903 New Hampshire Avenue
White Oak 66
Silver Spring, MD 20993

Dear Mr. Woods:

I am writing in response to your letter of May 11, 2011 concerning Lumigenix's genetic testing service.

As a provider of an informational service that enables individuals to access and to understand their personal genetic information, Lumigenix is committed to working with the United States Food and Drug Administration (FDA) to ensure that our service complies with all applicable legal and regulatory requirements.

When it comes to the appropriate regulation of personal genomics services, I believe that Lumigenix and the FDA share a common vision: to provide for the availability of highly accurate personalized genetic information in a manner that maximizes individual benefit and minimizes risk. Lumigenix has invested substantial time and energy in the design of our current service with this goal in mind. We look forward to working with the FDA to improve our product offerings and to participate in the development of a clear and reasonable system of oversight for the emerging field of personal genomics.

To that end, I would like to provide you with some additional information about Lumigenix and our current genetic testing service.

Our Products and Our Process. Lumigenix currently offers a single service divided into two products: the "introductory service" and the "comprehensive service." Each service uses genotype data (approximately 5,000 SNPs for the introductory service and approximately 700,000 SNPs for the comprehensive service) to generate a personalized genomic report. This report includes information on either 76 (introductory service) or 81 (comprehensive service) phenotypes for each individual.

Prior to ordering the Lumigenix service, a customer must acknowledge and agree to the Lumigenix Conditions of Use.[1] The Conditions of Use clearly indicate that Lumigenix's products are intended solely for informational, educational or research use, as discussed in more detail below.

Purchasers of both the Introductory and Comprehensive products are mailed a standard saliva collection kit. The kit includes return shipping materials included and clear instructions in multiple languages for the collection and shipment of the saliva sample.

The saliva sample collection kit also includes instructions for the customer to register his or her service with Lumigenix. Registration occurs online and must be completed before a customer's sample will be processed. The registration process includes a separate Consent Form which, as with the Conditions of Use, requires each customer to read, acknowledge and agree to important terms of use, including that the service is intended solely for informational, educational or research use and is not intended to be used for any diagnostic, clinical or medical purpose.

Following registration, at his or her convenience, the customer collects the saliva sample and ships it directly to a CLIA-certified laboratory for processing. The laboratory processes the samples and electronically transmits the resulting genetic data to Lumigenix. The lab then destroys the samples and no customer information is retained by the laboratory. This is done to ensure that the laboratory retains no potentially identifying information about Lumigenix customers following sample processing.

[1] See https://www.lumigenix.com/conditions.

Next, Lumigenix processes each customer's genetic data using publicly available and widely accepted curation and calculation methods[2] and generates a personalized report. The genome report contains information on either 76 (introductory service) or 81 (comprehensive service) phenotypes. Each customer's genomic report is reviewed by qualified Lumigenix personnel, including the Chief Technology Officer, Laboratory Director and Medical Director, to ensure that it meets specified quality control and data accuracy standards.

Once a report is reviewed and approved it is made available to the customer online via the Lumigenix website and secured through industry-standard authentication and encryption protocols. Customers may view the report online, download or print a summary of the report and download a complete copy of their raw (i.e., unanalyzed) genotype data. In addition, customers purchasing the comprehensive service receive regular informational updates as new scientific findings are incorporated into Lumigenix's curated database of genetic associations.

An Educational Service. Lumigenix's current products are intended to facilitate customer education and exploration. Our service appeals to individuals who, even after being advised of the limitations of genetic information, remain excited by the prospect of personal genomic discovery.

Our existing service is not intended to serve as a means to diagnose, cure, mitigate, treat or prevent any disease or other condition, and we have gone to great lengths to ensure that this fact is clearly conveyed to current and prospective customers.

For example, every page of our website contains the following language:

> DISCLAIMER: This service is not a test or kit designed to diagnose, treat or prevent a disease or medical condition and is not intended to be medical advice. This service has not been approved by the TGA[3] or FDA for diagnostic use.

Additional reminders emphasizing the educational nature of our service appear throughout the Lumigenix website and at key stages of the genetic testing process. We also maintain a webpage[4] dedicated to describing the limitations of personal genomics and our service, including the preliminary nature of much genetic research and the importance of ethnicity, family history and environmental factors in accurately interpreting the results of any genetic test.

While we have gone to considerable lengths to ensure that current and prospective customers understand that Lumigenix provides an educational service and not a clinical or medical genetic test, we are currently in the process of reviewing our website and other informational materials to identify means to reinforce this message in the clearest possible fashion. We would welcome any comments the FDA has on our informational materials.

In order to ensure there is no doubt about the educational purpose of our service, Lumigenix's current service intentionally excludes certain categories of genetic tests. For that reason, Lumigenix's does not currently include in its customers' genomic reports results from genotype data known to be associated with or to indicate:

- carrier status for a recessive disease (e.g., Cystic Fibrosis or Tay-Sachs disease);
- pharmacogenomic status related to an individual's likely response to certain medications (e.g., Warfarin or Clopidogrel); or
- a serious or untreatable illnesses with a large genetic component (e.g., breast cancer, Huntington's disease or Alzheimer's disease).

We understand that some individuals desire such results for their informational value. But we also acknowledge that the risks associated with personal genomics, including the risk that an individual will make an important medical or other decision without first consulting a healthcare professional, are not equal across all categories of genetic tests.

For that reason, Lumigenix has decided to focus its current service on providing personalized genetic information pertaining to genetic ancestry, non-medical traits and conditions, and certain relatively common medical- or health-related conditions that tend to be influenced by many genes and include a substantial environmental component.

From its inception, Lumigenix has considered carefully the concerns about personal genomics services raised by the FDA and commentators. We have undertaken a concerted effort to design our service to address those concerns and to minimize each

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[2] The curation and risk calculation processes are available at https://www.lumigenix.com/how/how.
[3] Therapeutic Goods Administration.
[4] See https://www.lumigenix.com/transparency.html.

individual customer's risk. As the public's desire for personalized genomic data grows, we continue to explore ways to provide more comprehensive genetic information in a responsible fashion, and we look forward to discussing that process with the FDA.

The Next Step. As we are all aware, the recent emergence of inexpensive and widely available personalized genomic data has created an unprecedented ability for individuals to examine their unique genetic code. This new paradigm of personal genomics presents tremendous opportunities, as well as significant challenges.

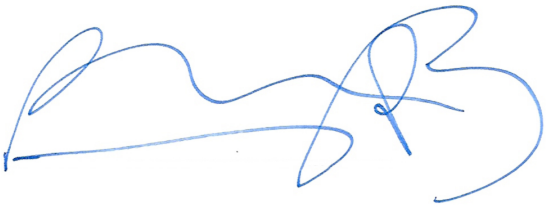
While we strongly believe that individuals should have the right to access their own genetic information, we believe in providing such access in a way that maximizes individual benefit while minimizing risk. We also share the FDA's goal of developing reasonable, predictable and consistent regulatory policies that balance safety and innovation in the area of personal genomics. We look forward to joining with the FDA and other personal genomics stakeholders to develop clear guidelines that will enable our industry to meet its customers' needs in a responsible fashion.

In the meantime, Lumigenix remains committed to providing an important educational resource to personal genomics consumers in compliance with applicable legal and regulatory requirements.

As a next step, we would appreciate the opportunity to meet with your office to discuss our current service and to answer any questions that you may have. In light of the fact that Lumigenix headquarter is based in Australia, I would appreciate the opportunity to schedule this meeting sufficiently far in advance to make appropriate travel arrangements. A meeting during the first half of August would be preferable.

I have included my direct contact information below and look forward to hearing from your office soon.

Regards,



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