



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Chinh Bach, Ph.D.  
Chief Executive Officer  
Consumer Genetics, LLC  
3350 Scott Blvd. Bldg. 2  
Santa Clara, CA 95054

**JUL 19 2010**

Dear Dr. Bach:

It has come to our attention that you are currently marketing the AsthmaGEN DNA Test, a home-use device that is intended to test a DNA variant that makes certain individuals unresponsive to long-term use of the most commonly prescribed asthma medications. The AsthmaGEN DNA Test appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act.

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for the AsthmaGEN DNA Test. We request that you provide us with the FDA clearance or approval number for the AsthmaGEN DNA Test. If you do not believe that you are required to obtain FDA clearance or approval for the AsthmaGEN DNA Test, please provide us with the basis for that determination.

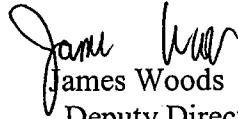
If you would like to meet with us to discuss whether there are tests you are promoting that do not require review by FDA and what information you would need to submit in order for your product to be legally marketed, let us know and we will schedule a meeting with you. Please direct your questions and response to:

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

We would appreciate a response within 15 days from the date of this letter. If you have any questions relating to this matter, please feel free to call Joshua Levin at 301-796-

6695, or access our website at <http://www.fda.gov> for general information relating to FDA's device requirements.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James Woods". The signature is written in a cursive style with a large initial "J" and "W".

James Woods  
Deputy Director  
Patient Safety and Product Quality  
Office of *In Vitro* Diagnostic  
Device Evaluation and Safety  
Center for Devices and Radiological Health