



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

James Plante
Founder and CEO
Pathway Genomics Corporation
4045 Sorrento Valley Blvd.
San Diego, CA 92121

MAY 10 2010

Dear Mr. Plante:

It has come to our attention that you are currently marketing the Pathway Genomics Genetic Health Report, a home-use saliva collection kit, intended to report customary and personal genetic health disposition results for more than 70 health conditions, including pharmacogenetics (prescription medication response), propensity for complex disease, and carrier status (pre-pregnancy health) information from which one can modify their health regime to live a healthier, longer life. The Genetic Health Report 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 Genetic Health Report. We request that you provide us with the FDA clearance or approval number for the Genetic Health Report. If you do not believe that you are required to obtain FDA clearance or approval for the Genetic Health Report, please provide us with the basis for that determination.

The requested information should be submitted 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 Cecily Jones at 301-796-6172, or access our web site at <http://www.fda.gov> for general information relating to FDA's device requirements.

Sincerely yours,

/S/

James Woods

Deputy Director

Patient Safety and Product Quality

Office of *In Vitro* Diagnostic

Device Evaluation and Safety

Center for Devices and Radiological Health