



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

Kenneth W. Friedenberg  
Owner  
Graceful Earth Inc.  
838 Kealahou Street  
Honolulu, HI 96825

**JUL 19 2010**

Dear Mr. Friedenberg:

It has come to our attention that you are currently marketing the Graceful Earth Alzheimer's Test, a home-use saliva collection kit, intended to report customary and personal genetic health disposition results for Alzheimer's Disease. 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 Alzheimer's Test. We request that you provide us with the FDA clearance or approval number for the Alzheimer's Test. If you do not believe that you are required to obtain FDA clearance or approval for the Alzheimer's 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:

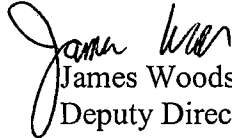
James L. Woods  
Deputy Director, Patient Safety and Product Quality  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
10903 New Hampshire Avenue  
White Oak 66  
Silver Spring, MD 20993

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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,

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