



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUL 19 2010

Lewis H. Bender
Chief Executive Officer
Interleukin Genetics, Inc.
135 Beaver Street
Waltham, MA 02452

Dear Mr. Bender:

It has come to our attention that you are currently marketing the Inherent Health, a genetic testing service, intended to help health professionals assess their patients' genetic results for a variety of genetic tests, decide on next steps, and integrate preventive genomic medicine into their practice. The Inherent Health 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 Inherent Health. We request that you provide us with the FDA clearance or approval number for the Inherent Health. If you do not believe that you are required to obtain FDA clearance or approval for the Inherent Health, please provide us with the basis for that determination.

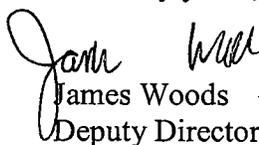
If you would like to meet with us to discuss whether there are tests you are promoting that do not require review by FDA and what information you would need to submit in order for your product to be legally marketed, let us know and we will schedule a meeting with you. Please direct your questions and 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 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 cursive script that reads "James Woods". The signature is written in black ink and is positioned to the left of the printed name.

James Woods
Deputy Director

Patient Safety and Product Quality

Office of *In Vitro* Diagnostic

Device Evaluation and Safety

Center for Devices and Radiological Health