DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Randy Farr
Chief Executive Officer
Healthspek LLC
6431 Annandale Cove
Brentwood, TN 37027

DEC 07 2015

Document Number: GEN1500807

Dear Mr. Farr:

It has come to our attention that you are currently marketing a direct-to-consumer test the Healthspek PGT, which is intended to test genes that affect drug metabolism. The Healthspek PGT 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 number for the Healthspek PGT. We request that you provide us with the FDA clearance number for the Healthspek PGT. If you do not believe that you are required to obtain FDA clearance for the Healthspek PGT, please provide us with the basis for that determination.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Randy Farr,
Healthspek LLC

If you have questions relating to this matter, please feel free to call Freddy Tita-Nwa at 301-796-6213, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

James L. Woods
Deputy Director Patient Safety
And Product Quality
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health