DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Richard Zimmer III
CEO
DNA4Life
c/o MyGenesRx
22811 Highway 98, Suite 5
Fairhope, AL 36532

NOV 0 2 2015

Document Number: GEN1500800

Dear Mr. Zimmer:

It has come to our attention that you are currently marketing the Pharmacogenetic Report, which is marketed directly to patients and is intended to predict how patients will respond to more than 120 of the most commonly prescribed medications. The Pharmacogenetic 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 number for the Pharmacogenetic Report. We request that you provide us with the FDA clearance number for the Pharmacogenetic Report. If you do not believe that you are required to obtain FDA clearance for the Pharmacogenetic Report, 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. Richard Zimmer III
DNA4Life

If you have questions relating to this matter, please feel free to call Joshua Levin at 301-796-6695, 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