DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 10 2010

Navigenics
c/o Vance Vanier, M.D.
President and CEO
1001 E. Hillsdale Blvd, Suite 550
Foster City, CA 94404

Re: Navigenics Health Compass

Dear Dr. Vanier:

The United States Food and Drug Administration (FDA) has determined that your firm manufactures Navigenics Health Compass. The Navigenics Health Compass is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h) because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

In 1976, Congress enacted the Medical Device Amendments (MDA), which amended the Act to provide for premarket regulation of medical devices intended for use in humans. This premarket review of medical devices enables FDA to protect the public from medical products that may pose an unreasonable risk of harm. It is important that they be analytically and clinically accurate so that individuals are not misled by incorrect test results or unsupported clinical interpretations. Premarket review allows for an independent and unbiased assessment of a diagnostic test's ability to generate test results that can reliably be used to support good healthcare decisions.

Navigenics has never submitted information on the analytical or clinical validity of its tests to FDA for clearance or approval. However, your website states that the Navigenics Health Compass provides personalized information on which medications are more likely to work best for you given your genetic makeup, including warfarin and clopidogrel. It also states that the data generated from the Navigenics Health Compass provide patients with genetic predispositions for important health conditions and medication sensitivities. Consumers may make medical decisions in reliance on this information. Furthermore, Navigenics distributes a collection kit directly to the consumer through your website.

We are not aware that you have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). In addition, we are not aware that you have notified the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b).

You should take prompt action to respond to this letter. 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 for the other uses, let us know and we will schedule a meeting with you. Please direct your questions and response to: **James L. Woods, Food and Drug Administration, 10903 New Hampshire Avenue, WO66-5688, Silver Spring, MD 20993 or** facsimile at **(301) 847-8514.**

General information on obtaining approval or clearance for devices is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html.

This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law. FDA is available to discuss other obligations for medical device manufacturers with you.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Device and Radiological Health