DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 21, 2015

Mr. Jim Plante
Founder and CEO
Pathway Genomics, Inc.
4755 Nexus Center Drive
San Diego, CA 92121

Document Number: GEN1500674

Dear Mr. Plante:

It has come to our attention that you are currently marketing CancerIntercept™ Detect, which is a non-invasive blood test intended for use as a screening tool for the early detection of up to 10 different cancer types in high risk populations. CancerIntercept™ Detect 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. It appears that you are offering CancerIntercept™ Detect under a direct-to-consumer type model. Under this model, you ship blood collection tubes, a medical device, for use with CancerIntercept™ Detect.

We have conducted a review of our files and have been unable to identify any Food and Drug Administration (FDA) records reflecting the approval, clearance, or listing of these devices. We have also examined published literature and have not found any published evidence that this test or any similar test has been clinically validated as a screening tool for early detection of cancer in high risk individuals. We have reviewed the information presented on your website in the white paper, entitled "*Liquid Biopsy for the Detection and Monitoring of Cancer: Analysis of 96 Hotspot Mutations via Plasma Derived Circulating Tumor DNA*," dated September 2015. It is unclear how the literature that you cited, addressing the presence of circulating tumor DNA (ctDNA) in already-diagnosed patients, is adequate to support the expansive claims of screening for early cancer detection using ctDNA in undiagnosed patients for up to 10 different cancers with the CancerIntercept™ Detect.

Based on our review of your promotional materials and the research publication cited above, we believe you are offering a high risk test that has not received adequate clinical validation and may harm the public health. We would like to discuss with you your offer of the CancerIntercept™ Detect and the associated blood specimen collection device, and any validation strategies you have undertaken beyond those reported in the publications cited in your white paper, including your determination of the test's clinical sensitivity and specificity and the corresponding positive and negative predictive values for its claimed intended use. Given the importance of your claims, we request an acknowledgement of receipt of this letter and a proposed timeline for meeting with the FDA within 15 business days.

We look forward to discussing this with you and are committed to working with you as we strive to protect the public health without unnecessarily imposing regulatory burdens on the marketing of products of potential clinical importance.

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, WO66-4684
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

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,

Donald J. St Pierre -S

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