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

Kenneth Fine, M.D.
Medical Director and Director of Operations
EnteroLab Reference Laboratory
10875 Plano Rd. Suite 123
Dallas, TX 75238

Dear Dr. Fine:

It has come to our attention that you are currently marketing the Gene Test for Gluten Sensitivity/Celiac Sprue, a home-use device that is intended to identify the presence of one or more genes that have been associated with having gluten sensitivity, celiac sprue, and other autoimmune syndromes. The Gene Test for Gluten Sensitivity/Celiac Sprue 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 Gene Test for Gluten Sensitivity/Celiac Sprue. We request that you provide us with the FDA clearance or approval number for the Gene Test for Gluten Sensitivity/Celiac Sprue. If you do not believe that you are required to obtain FDA clearance or approval for the Gene Test for Gluten Sensitivity/Celiac Sprue, 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 Joshua Levin at 301-796-

6695, or access our website at http://www.fda.gov for general information relating to FDA's device requirements.

Sincerely yours,

James Woods
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostic
Device Evaluation and Safety
Center for Devices and Radiological Health