



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

December 28, 2011

Nathan A. Beaver  
Partner  
Foley & Lardner LLP  
C/o Marker Test, Inc.  
3000 K St. NW, Ste 500  
Washington, DC 20007

Dear Mr. Beaver:

Please refer to your June 27 and August 31, 2011 letters requesting informal determination from the Center for Drug Evaluation and Research (CDER) regarding the regulatory status of the product, Marker-System.

I have reviewed the product labeling and information you enclosed with your letters and consulted with CDER's Office of Compliance and the Division of Nonprescription Clinical Evaluation. Based on the information you provided, we agree that the product is not "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals as defined under 201(g) of the Food, Drug, and Cosmetics Act. Therefore, it is our opinion that the Marker-System product, as described in your submissions, should not be regulated as a drug.

This letter represents CDER's opinion as to the regulatory status of the Marker-System based on the information you provided in your letters. Please note that final decisions regarding the classification of products as drugs, biologics, devices, or combination products falls within the purview of FDA Office of Combination Products (OCP). If you desire a formal and binding jurisdictional determination regarding the classification of the Marker-System product, you should submit a formal Request for Designation to OCP.

Please also note that this letter does not constitute approval or endorsement of the Marker-System by CDER.

If you have any questions, please call me at (301) 796-0630.

Sincerely,

A handwritten signature in black ink that reads "Ayoub Suliman". The signature is written in a cursive style with a large initial 'A'.

Ayoub Suliman, Pharm.D.  
Product Jurisdiction Officer  
Office of Executive Programs  
Center for Drug Evaluation and Research

Cc: Christopher Scannell, MBA  
President and CEO  
Marker Test, Inc.