MEMORANDUM

To: Glenn Lesser, M.D.
Int Md-Hematology_Oncology

From: Chair,
Institutional Review Board

Date: 3/5/2015

Subject: Human Protocol: BG03-161
A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients

Study Documents:
Protocol Version: 60A02 Am 19 protocol without tracking.docx; Informed Consent Version: Updated Consent CR 2007 60A02 (approved); Advertisements: BG03-161 Advertisement; Other Documents: University of Miami 2010 Approval Letter

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 3/5/2015 and will expire on 3/4/2016. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

This application indicates that advertising materials will be used for research purposes. Please consult with Creative Communications to ensure the appropriate visual identity is put forth.

This research, which was originally approved by the Full Board, is being renewed by the IRB under Expedited Review, Category 8c. The research has been closed to the accrual of new subjects and all subjects have completed intervention/interaction. Renewal is granted for data analysis only.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.


Richard Weinberg, M.D.