Analysis of Proposed Consent Order to Aid Public Comment *In the Matter of Bioque Technologies, Inc.*, File No. 082 3095

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Bioque Technologies, Inc., Vittorio A. Bonomo, and Christine A. Guilman (together, "Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of Serum GV, a topical serum that, according to its label, contains, among other ingredients, extract of annona muricata, also known as graviola, derived from the soursop or guanabana tree. According to the FTC complaint, Respondents represented that Serum GV is an effective treatment for skin cancer, including melanoma, and that it prevents melanoma. The complaint alleges that Respondents failed to have substantiation for these claims. Also according to the FTC complaint, Respondents represented that Serum GV is recognized by the medical profession as an effective treatment for skin cancer and that it is clinically proven to prevent or treat melanoma. The complaint alleges that these claims are false and misleading because Serum GV is not recognized by the medical profession as an effective treatment for skin cancer and is not clinically proven to prevent or treat melanoma. The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires Respondents to have competent and reliable scientific evidence substantiating any claims that a covered product or service is an effective treatment for skin cancer, including melanoma; prevents melanoma; is recognized by the medical profession as an effective treatment for skin cancer; or is clinically proven to prevent or treat melanoma. The provision further requires that such claims be true and non-misleading. A "covered product or service" is defined in the order as "any health-related service or program; or any food, dietary supplement, device, or drug, including, but not limited to, Serum GV."

Part II of the proposed order requires the Proposed Respondents to possess competent and reliable scientific evidence for any claims about the absolute or comparative benefits, performance, efficacy, safety, or side effects of any covered product or service. The claims also must be truthful and non-misleading.

Part III of the proposed order prohibits Respondents from making future misrepresentations about the existence, contents, validity, results, conclusions, or interpretations of any test or study.

Part IV of the proposed order provides that the order does not prohibit Respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug

application approved by the FDA and representations for any product that are specifically permitted in labeling for that product by regulations issues by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires Respondents to provide the FTC with a list of all consumers that they know purchased Serum GV and prohibits Respondents from using or disclosing the consumer information, except to a law enforcement agency or as required by law.

Part VI of the proposed order requires Respondents to send to the consumers identified in Part V a notification letter drafted by the FTC to inform them about the consent agreement.

Part VII of the proposed order provides for the payment of \$9,035.85, the full amount of sales of the product, to the Commission.

Parts VIII through XII of the proposed order require Respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure (for the corporate respondent) and changes in employment (for the individual respondents) that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.