Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Elation Therapy, Inc., et al., File No. 072-3142

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Elation Therapy, Inc., a corporation, and Robert Rutledge, individually and as an officer of Elation Therapy (together, "respondents").

The proposed consent order has been placed on the public record for thirty (30) days for reception 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 Elation Therapy Natural Progesterone Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that Elation Therapy Natural Progesterone Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-inducted endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The complaint alleges that respondents failed to have substantiation for these claims. 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 claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III 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; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII 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 and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX 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. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.