Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Telomerase Activation Sciences, Inc., et al., Matter No. 142 3103

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order as to Telomerase Activation Sciences, Inc. and Noel Thomas Patton (collectively "respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 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 order.

This matter involves respondents' advertising for TA-65MD, a product that comes in capsule and powder forms, and TA-65 for Skin ("TA-65 Skin"), a topical cream product. The complaint alleges that respondents violated Sections 5(a) and 12 of the FTC Act by making false or unsubstantiated health or performance claims that: TA-65MD and TA-65 Skin reverse aging; TA-65MD prevents and repairs DNA damage; TA-65MD restores aging immune systems; TA-65MD increases bone density; TA-65MD reverses the effects of aging, including improving skin elasticity, increasing energy and endurance, and improving vision; TA-65MD prevents or reduces the risk of cancer; TA-65 Skin reverses the effects of aging, including improving skin elasticity; and TA-65 Skin decreases recovery time of the skin after medical procedures. The complaint also alleges that respondents claimed that some of the above performance claims were clinically or scientifically proven.

The complaint further alleges that respondents misrepresented that a 2012 paid-for segment on *The Suzanne Show* featuring TA-65MD was independent, educational programming and not paid commercial advertising. Additionally, the complaint alleges that respondents deceptively represented that consumers appearing in advertisements were independent users of TA-65MD, expressing their impartial views of satisfaction. According to the complaint, respondents failed to disclose that these consumer endorsers received compensation, including free TA-65MD. Finally, the complaint alleges that by providing promotional materials that had false or unsubstantiated health or performance claims to marketers of other products containing TA-65MD, respondents provided these other marketers the means and instrumentalities to engage in deceptive acts and practices.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The order applies to marketing claims for any covered product, defined as TA-65MD and TA-65 Skin or any other drug, food, dietary supplement, or cosmetic. As additional fencing-in relief, the order requires respondents to provide a notice to all of its licensees authorized to advertise, market, or sell any covered product, monitor certain high-selling licensees, and follow appropriate recordkeeping, compliance reporting, and document preservation requirements.

Provision I prohibits any representation that a covered product reverses human aging; prevents or repairs DNA damage; restores aging immune systems; increases bone density; reverses the effects of aging, including improving skin elasticity, increasing energy and endurance, and improving vision; decreases recovery time of the skin after medical procedures;

prevents or reduces the risk of cancer; or cures, mitigates, or treats any disease unless the representation is non-misleading and respondents possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. The definition of competent and reliable scientific evidence in Provision I specifies human clinical testing and requires that the testing be sufficient in quality and quantity, based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must (1) be randomized, double-blind, and placebo-controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, respondents must maintain all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing.

Provision II prohibits representations regarding the health benefits, performance, efficacy, safety, or side effects of any covered product unless the representation is non-misleading and respondents possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true. Provision II defines competent and reliable scientific evidence as tests, analyses, research, or studies: (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, when such experts would generally require such human clinical testing to substantiate that the representation is true. When such tests or studies are human clinical tests or studies, respondents must maintain all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing.

Provision III prohibits misrepresentations that any covered product is clinically or scientifically proven to reverse human aging, prevent or repair DNA damage, restore aging immune systems, or increase bone density. Provision III also prohibits any misrepresentation that the performance or benefits of any product are scientifically or clinically proven or about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Provision IV is a provision for FDA-approved claims.

Provision V prohibits misrepresentations in connection with the marketing, advertising, or promoting of any product, service, or program that paid commercial advertising is independent programming.

Provision VI prohibits any representation about any user, consumer, or endorser of a covered product without disclosing, clearly and conspicuously, and in close proximity to that representation, any unexpected material connection between such endorser and (1) any respondent; or (2) any other individual or entity affiliated with the product. "Unexpected material connection" means any relationship that might materially affect the weight or credibility of the testimonial or endorsement and that would not reasonably be expected by consumers.

Provision VII prohibits misrepresentations regarding the status of any endorser or person providing a review of a product, including a misrepresentation that the endorser or reviewer is an independent or ordinary user of the product.

Provision VIII prohibits respondents from providing the means and instrumentalities to make any false or misleading statement of material fact, including the representations prohibited by Provisions I to III. "Means and instrumentalities" mean any information, document, or article referring or relating to any covered product, including any advertising, labeling, promotional, or purported substantiation materials, for use by a licensee to market or sell any covered product.

Provision IX, triggered when the human clinical testing requirement in Provisions I or II applies, requires that respondents secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a reliably reported test (defined as a test that is published in a peer-reviewed journal) that was not conducted, controlled, or sponsored by, with, or on behalf of any respondent or by any supplier or manufacturer of the product. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Provision X mandates that respondents acknowledge receipt of the order, distribute the order to principals, officers, and certain employees and agents, and obtain signed acknowledgments from them.

Provision XI requires that respondents submit compliance reports to the FTC 60 days after the order's issuance and submit notifications when certain events occur for 10 years.

Provision XII requires that respondents create and retain certain records for 10 years.

Provision XIII provides for the FTC's continued compliance monitoring of respondents' activities during the order's effective dates.

Provision XIV requires that respondents notify their licensees, monitor their highest-selling licensees' advertising to ensure compliance with Provisions I through III, and suspend any licensee who makes any prohibited claims. Respondents must terminate any licensee who continues to make prohibited claims. There are two limited exceptions to the monitoring requirement: (1) representations during private consultations between a licensee and one of the licensee's patients about the potential safety, health benefits, performance, efficacy, or side effects of a covered product; and (2) representations about the potential safety, health benefits, performance, efficacy, or side effects of a covered product by a licensee who has purchased a covered product solely for incorporation into the licensee's own product and markets that product without any involvement by respondents.

Provision XV requires that respondents send a notice to all customers who purchased directly from them TA-65MD or TA-65 Skin within one year prior to the issuance of the order or through a currently active enrollment in a continuity or autoship program.

Provision XVI provides that, with exceptions, the order will terminate in 20 years.

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