ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of GeneLink, Inc., File No. 112 3095

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from GeneLink, Inc., also doing business as GeneLink Biosciences, Inc. ("GeneLink"). 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 purported genetically customized nutritional supplements and skin repair serum products, which GeneLink and its co-respondent and former subsidiary, foru™ International Corporation, formerly known as GeneWize Life Sciences, Inc. ("foru™"), sold through a multi-level marketing ("MLM") network. According to the FTC complaint, GeneLink and foru™ represented that genetic disadvantages identified through the companies' DNA assessments are scientifically proven to be mitigated by or compensated for with the companies' nutritional supplements. The complaint alleges that this claim is false and thus violates the FTC Act. The FTC complaint also charges that the companies represented that these custom-blended nutritional supplements: (1) effectively compensate for genetic disadvantages identified by respondents' DNA assessments, thereby reducing an individual's risk of impaired health or illness, and (2) treat or mitigate diabetes, heart disease, arthritis, and insomnia. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act.

With regard to the purported genetically customized skin repair serum products, the FTC complaint charges that the companies represented that the products are scientifically proven to reduce the appearance of wrinkles and improve skin firmness; and enhance or diminish aging predispositions, including collagen breakdown, sun damage, and oxidative stress. The complaint alleges that these claims are false and thus violate the FTC Act.

Additionally, the complaint alleges that the companies provided advertisements and promotional materials to their MLM affiliates for use in the marketing and sale of their genetically customized nutritional supplements and skin repair serum products. The complaint alleges that the companies thereby provided their affiliates with means and instrumentalities to further the deceptive and misleading acts and practices at issue.

Finally, the FTC complaint alleges that the companies' acts and practices related to data security were unfair and deceptive. The companies collected personal information, including names, addresses, email addresses, telephone numbers, dates of birth, Social Security numbers, bank account numbers, credit card account numbers, and genetic information. They represented to consumers that they implemented reasonable

and appropriate measures to secure consumers' personal information. The complaint alleges the companies failed to provide reasonable and appropriate security for consumers' personal information. According to the complaint, among other things, the companies:

(1) Failed to implement reasonable policies and procedures to protect the security of consumers' personal information collected and maintained by respondents;

(2) Failed to require by contract that service providers implement and maintain appropriate safeguards for consumers' personal information;

(3) Failed to provide reasonable oversight of service providers, for instance by requiring that service providers implement simple, low-cost, and readily available defenses to protect consumers' personal information;

(4) Created unnecessary risks to personal information by: (a) maintaining consumers' personal information in clear text; (b) providing respondents' employees, regardless of business need, with access to consumers' complete personal information; (c) providing service providers with access to consumers' complete personal information, rather than, for example, to fictitious data sets, to develop new applications; (d) failing to perform assessments to identify reasonably foreseeable risks to the security, integrity, and confidentiality of consumers' personal information on respondents' network; and (e) providing a service provider that needed only certain categories of information for its business purposes with access to consumers' complete personal information; and

(5) Did not use readily available security measures to limit wireless access to their network.

The complaint further alleges respondents' failure to provide reasonable oversight of service providers and respondents' failure to limit employees' access to consumers' personal information resulted in a vulnerability that, until respondents were alerted by an affiliate, provided that affiliate with the ability to access the personal information of every foru™ customer and affiliate in respondents' customer relationship management database. The personal information that could have been accessed included consumers' names, addresses, email addresses, telephone numbers, dates of birth, and Social Security numbers. The complaint alleges that respondents' practices were likely to cause substantial injury to consumers, were not reasonably avoidable by consumers, and were not outweighed by countervailing benefits to consumers or competition.

The proposed consent order contains provisions designed to prevent GeneLink from engaging in similar acts or practices in the future. The order covers representations made in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce. First, the

order defines Covered Product as any drug, food, or cosmetic that is: (a) customized or personalized for a consumer based on that consumer's DNA or other genetic assessment, including, but not limited to, the nutritional supplement and skin repair serum products at issue; or (b) promoted to modulate the effect of genes. Second, it defines Essentially Equivalent Product to mean a product that contains the identical ingredients, except for inactives, in the same form, dosage, and route of administration as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product. Third, it defines adequate and well-controlled human clinical study to mean a human clinical study that is randomized and adequately controlled; utilizes valid end points generally recognized by experts in the relevant disease field; yields statistically significant between-group results; and is conducted by persons qualified by training and experience to conduct such a study. This definition requires that the study be double-blind and placebo-controlled; however, this definition provides an exception for any study of a conventional food if the respondent can demonstrate that placebo control or blinding cannot be effectively implemented given the nature of the intervention. Fourth, it defines Covered Assessment as any genetic test or assessment, including but not limited to, the companies' current DNA assessments. Finally, the order defines Licensee as a person or entity, including a sublicensee (*e.g.*, foru™) with whom respondent or its licensee has a business agreement. With respect to information security, the proposed order closely follows the Commission's previous data security orders.

Part I of the consent order is designed to address GeneLink's specific claims about diseases and serious health conditions by prohibiting the company from making any representation that any Covered Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including any representation that such product will treat, prevent, mitigate, or reduce the risk of diabetes, heart disease, arthritis, or insomnia, unless such representation is non-misleading and, at the time the representation is made, GeneLink possesses and relies upon competent and reliable scientific evidence, at least two adequate and well-controlled human clinical studies of the Covered Product, or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Further, claims that a Covered Product effectively treats or prevents a disease in persons with a particular genetic variation, must be conducted on subjects with that genetic variation because persons with the particular genetic variation may respond differently to the Covered Product than do persons without the variation. The substantiation standard imposed under this Part is reasonably necessary to ensure that any future claims about diseases and serious health conditions made by the named respondents are not deceptive; this standard does not necessarily apply to firms not under order.

Part II of the consent order prohibits GeneLink from making any representation about the health benefits, performance, or efficacy of any Covered Product or any

Covered Assessment, unless the representation is non-misleading, and proposed respondents rely on competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the claim is true.

Part III of the consent order addresses claims regarding scientific research. It prohibits GeneLink, with regard to any Covered Product or any Covered Assessment, from misrepresenting the existence, contents, validity, results, or conclusions of any test, study, or research. This Part also prohibits GeneLink from representing that the benefits of any Covered Product or any Covered Assessment are scientifically proven.

Part IV of the consent order provides that nothing in the order shall prohibit GeneLink from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990, or that is permitted under sections 303-304 of the Food and Drug Administration Modernization Act of 1997, which, under certain circumstances, permit claims about health and nutrient content as long as those claims are based on current, published, authoritative statements from certain federal scientific bodies (*e.g.*, National Institutes of Health, Centers for Disease Control) or from the National Academy of Sciences.

Part V of the consent order prohibits GeneLink from providing any person or entity with means and instrumentalities that contain any representations prohibited under Parts I through III of the order.

Part VI of the consent order requires GeneLink to establish, implement, and maintain a program to monitor its affiliates' compliance with Parts I through III of the proposed order. In particular, for GeneLink's top 50 revenue-generating affiliates, on at least a monthly basis, the company must monitor and review such affiliates' websites and also conduct online monitoring and review of the Internet for any representations by such affiliates. This Part also requires GeneLink to terminate and withhold payment from an affiliate within seven days of reasonably concluding that the affiliate made representations that the affiliate knew or should have known violated Parts I, II, or III of the order. Finally, this Part requires GeneLink to create, maintain, and make available to FTC representatives within 14 days of receipt of a written request, reports sufficient to show compliance with this Part.

Part VII of the consent order prohibits GeneLink from misrepresenting the extent to which they maintain and protect the privacy, confidentiality, security, or integrity of any personal information collected from or about consumers.

Part VIII of the consent order requires GeneLink to establish and maintain a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. The security program must contain administrative, technical, and physical

safeguards appropriate to GeneLink's size and complexity, nature and scope of its activities, and the sensitivity of the information collected from or about consumers. Specifically, the proposed order requires GeneLink to:

- designate an employee or employees to coordinate and be accountable for the information security program;
- identify material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks;
- design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures;
- develop and use reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from GeneLink, and require service providers by contract to implement and maintain appropriate safeguards; and
- evaluate and adjust its information security program in light of the results of testing and monitoring, any material changes to operations or business arrangement, or any other circumstances that it knows or has reason to know may have a material impact on its information security program.

Part IX of the consent order requires GeneLink to obtain biennial independent assessments of their security programs for 20 years.

Part X of the consent order requires dissemination of the order to officers, to Scientific Advisory Board members, to licensees, and to employees having managerial responsibilities with respect to the subject matter of the order.

Part XI of the consent order requires GeneLink to keep, for a prescribed period, copies of all materials relied upon to prepare the assessment and any other materials relating to GeneLink's compliance with Parts VIII and IX, as well as relevant advertisements and promotional materials, including marketing and training materials distributed to licensees and affiliates.

Parts XII and **XIII** of the consent order require GeneLink to notify the Commission of changes in corporate structure that might affect compliance obligations under the order, and to file compliance reports. **Part XIV** provides that the order will terminate after twenty (20) years, with certain exceptions.

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 their terms in any way.