UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	**FILE NO. 112 3095**
GENELINK, INC.,	)	
a corporation, also d/b/a	)	**AGREEMENT CONTAINING**
GENELINK BIOSCIENCES, INC.	)	**CONSENT ORDER**
	)	

The Federal Trade Commission ("Commission") has conducted an investigation of certain acts and practices of GeneLink, Inc., a corporation, also doing business as GeneLink Biosciences, Inc. ("respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between GeneLink, Inc., by its duly authorized officers, and counsel for the Commission that:

1. Proposed respondent GeneLink, Inc. is a Pennsylvania corporation with its principal office or place of business at 8250 Exchange Drive, Suite 120, Orlando, Florida 32809.

2. Proposed respondent neither admits nor denies the allegations in the draft complaint, other than the jurisdictional facts, by entering into this agreement.

3. Proposed respondent waives:

   a. Any further procedural steps;

   b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

   c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve

its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

6. Proposed respondent has read the draft complaint and consent order. Proposed respondent understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" means GeneLink, Inc., a corporation, also doing business as GeneLink Biosciences, Inc., its successors and assigns, and its officers, agents, representatives, and employees.

2. "Commerce" means as defined in Section 4 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 44.

3. "Covered Product" means any drug, food, or cosmetic that is: (a) customized or personalized for a consumer based on that consumer's DNA or SNP (single nucleotide polymorphism) assessment, including, but not limited to, LifeMap ME DNA Customized Nutritional Supplements, GeneWize Nutritional Supplements, LifeMap ME DNA Customized Skin Repair Serum, and GeneWize Customized Skin Repair Serum; or (b) promoted to modulate the effect of genes.

4. "Covered Assessment" means any genetic test or assessment, including, but not limited to, the Healthy Aging Assessment and LifeMap Healthy Aging Assessment.

5. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), 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.

6. "Drug" means as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. "Food" means as defined in Section 15(b) of the FTC Act, 15 U.S.C. § 55(b).

8. "Cosmetic" means as defined in Section 15(e) of the FTC Act, 15 U.S.C. § 55(e).

9. "Adequate and well-controlled human clinical study" means 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. Such study shall be double-blind and placebo-controlled; *provided, however, that*, any study of a conventional food need not be placebo-controlled or double-blind if placebo control or blinding cannot be effectively implemented given the nature of the intervention. For the purposes of this proviso, "conventional food" does not include any dietary supplement, any customized or personalized product based on a consumer's DNA or SNP assessment, or any product promoted to modulate the effect of genes. Respondent shall have the burden of proving that placebo-control or blinding cannot be effectively implemented.

10. "Endorsement" means as defined in the Commission's Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.0.

11. "Licensee" means a person or entity, including a sublicensee, with whom respondent or its licensee has a business agreement.

12. "Affiliate" means any person or entity who participates in an Affiliate Program.

13. "Affiliate Program" means any arrangement whereby any person or entity: (a) provides respondent with, or refers to respondent, potential or actual customers; or (b) otherwise markets, advertises, or offers for sale any product or service on behalf of respondent.

14. "Personal Information" shall mean individually identifiable information from or about an individual consumer, including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name; (d) a telephone number; (e) a Social Security number; (f) a bank account, debit card, or credit card account number; (g) a persistent identifier, such as a customer number held in a "cookie" or processor serial number; or (h) clinical laboratory testing information, including test results. For the purpose of this provision, a "consumer" shall mean any person, including, but not limited to,

any user of respondent's services, any employee of respondent, or any individual seeking to become an employee, where "employee" shall mean an agent, servant, salesperson, associate, independent contractor, or other person directly or indirectly under the control of respondent.

15. The term "including" in this order means "without limitation."

16. The terms "and" and "or" in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, mitigate, or reduce the risk of diabetes, heart disease, arthritis, or insomnia, unless the representation is non-misleading and, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part I, "competent and reliable scientific evidence" shall consist of 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; *provided that*, if the respondent represents that such product is effective in the diagnosis, cure, mitigation, treatment, prevention, or the reduction of risk of disease for persons with a particular genetic variation or single nucleotide polymorphism ("SNP"), then studies required under this Part I shall be conducted on human subjects with such genetic variation or SNP. Respondent shall have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or any Covered Assessment, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, other than representations covered under Part I of this order, about the health benefits, performance, or efficacy of any Covered Product or any Covered Assessment, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon 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 representation is true. For purposes of this Part II, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or any Covered Assessment, in or affecting commerce, shall not misrepresent, in any manner, directly or indirectly, expressly or by implication, including through the use of endorsements:

A. The existence, contents, validity, results, or conclusions of any test, study, or research; or

B. That the benefits of any Covered Product or Covered Assessment are scientifically proven.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in Parts I through III of this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997; and

B. Nothing in Parts I through III of this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or any Covered Assessment, in or affecting commerce, shall not provide to any person or entity the means and instrumentalities with which to make, directly or by implication, any representations prohibited by Parts I through III of this order. For purposes of

this Part, "means and instrumentalities" shall mean any information, document, or article referring or relating to any Covered Product or any Covered Assessment, including, but not limited to, any advertising, labeling, promotional, or purported substantiation materials, for use by licensees or affiliates in their marketing of any Covered Product or any Covered Assessment in or affecting commerce.

VI.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, advertising, labeling, promotion, offering for sale, sale, or distribution of any product or service, in or affecting commerce, shall take steps sufficient to ensure compliance with Parts I through III of this order. Such steps shall include, at a minimum:

A. Establishing, implementing, and thereafter maintaining a system to monitor and review its affiliates' representations and disclosures to ensure compliance with Parts I through III of this order. The system shall be implemented as follows:

1. No later than thirty (30) days after the date of service of this order, and, on a semi-annual basis thereafter, respondent shall determine those affiliates that generate the most sales for respondent. For respondent's top fifty (50) revenue-generating affiliates, respondent shall:

(a) Monitor and review each affiliate's web sites on at least a monthly basis at times not disclosed in advance to its affiliates and in a manner reasonably calculated not to disclose the source of the monitoring activity at the time it is being conducted; and

(b) Conduct online monitoring and review of the Internet on at least a monthly basis, including, but not limited to, social networks such as Facebook, microsites such as Twitter, and video sites such as YouTube, for any representations by such affiliates.

2. For the remainder of respondent's affiliates, no later than thirty (30) days after the date of service of this order, and, on a semi-annual basis thereafter, respondent shall select a random sample of fifty (50) affiliates. Respondent shall:

(a) Monitor and review each of these randomly selected affiliates' web sites on at least a monthly basis at times not disclosed in advance to its affiliates and in a manner reasonably calculated not to disclose the source of the monitoring activity at the time it is being conducted; and

(b) Conduct online monitoring and review of the Internet on at least a monthly basis, including, but not limited to, social networks such

as Facebook, microsites such as Twitter, and video sites such as YouTube, for any representations by such affiliates.

B. Within seven (7) days of reasonably concluding that an affiliate has made representations that the affiliate knew or should have known violated Parts I, II, or III of this order, respondent shall terminate the affiliate from any affiliate program and cease payment to the affiliate; *provided, however*, that nothing in this subpart shall prevent respondent from honoring respondent's payment obligation to an affiliate pursuant to a contract executed by the affiliate and respondent prior to the date of service of the order; and

C. Creating, and thereafter, maintaining, and within fourteen (14) days of receipt of a written request from a representative of the Federal Trade Commission, making available for inspection and copying, reports sufficient to show compliance with this Part of the order.

VII.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, advertising, labeling, promotion, offering for sale, sale, or distribution of any product or service, in or affecting commerce, shall not misrepresent in any manner, expressly or by implication, the extent to which it maintains and protects the privacy, confidentiality, security, or integrity of Personal Information collected from or about consumers.

VIII.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, shall, no later than the date of service of this order, establish and implement, and thereafter 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. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the Personal Information respondent collects from or about consumers, including:

A. The designation of an employee or employees to coordinate and be accountable for the information security program;

B. The identification of 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 assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including

network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures;

C. The design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures;

D. The development and use of reasonable steps to select and retain service providers capable of appropriately safeguarding Personal Information received from respondent, and requiring service providers by contract to implement and maintain appropriate safeguards; and

E. The evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by subpart C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

IX.

IT IS FURTHER ORDERED that, in connection with its compliance with Part VIII of this order, respondent shall obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional who uses procedures and standards generally accepted in the profession. Professionals qualified to prepare such assessments shall be: a person qualified as a Certified Information System Security Professional (CISSP) or as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty (180) days after service of the order for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment shall:

A. Set forth the specific administrative, technical, and physical safeguards that respondent has implemented and maintained during the reporting period;

B. Explain how such safeguards are appropriate to respondent's size and complexity, the nature and scope of its activities, and the sensitivity of the Personal Information collected from or about consumers;

C. Explain how the safeguards that have been implemented meet or exceed the protections required by Part VIII of this order; and

D. Certify that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of Personal Information is protected and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies. The respondent shall provide its initial Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been completed. All subsequent biennial Assessments shall be retained by respondent until the order is terminated and provided to the Associate Director for Enforcement within ten (10) days of request. Unless otherwise directed by a representative of the Commission in writing, the initial Assessment, and any subsequent Assessments requested, shall be sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *In the Matter of GeneLink, Inc.*, FTC File No. 112 3095. *Provided, however*, that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at Debrief@ftc.gov.

X.

IT IS FURTHER ORDERED that respondent GeneLink, Inc., and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, Scientific Advisory Board members, and licensees, and to employees having managerial responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent GeneLink, Inc., and its successors and assigns, shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XI.

IT IS FURTHER ORDERED that respondent GeneLink, Inc., and its successors and assigns, shall maintain and, upon request, make available to a representative to the Commission for inspection and copying:

A. For a period of three (3) years after the date of preparation of each Assessment required under Part IX of this order, all materials relied upon to prepare the Assessment, whether prepared by or on behalf of respondent, including, but not limited to, all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials relating to respondent's compliance with Parts VIII and IX of this order, for the compliance period covered by such Assessment;

B. Unless covered by Part XI.A, for a period of five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Commission for inspection and copying:

1. All advertisements and promotional materials containing the representation, including, but not limited to, all marketing and training materials distributed to licensees and affiliates;

2. All materials that were relied upon in disseminating the representation; and

3. All tests, reports, studies, surveys, demonstrations, or other evidence in that respondent's possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

XII.

IT IS FURTHER ORDERED that respondent GeneLink, Inc., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent GeneLink, Inc., and its successors and assigns, learns less than thirty (30) days prior to the date such action is to take place, respondent GeneLink, Inc., and its successors and assigns, shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *In the Matter of GeneLink, Inc.*, FTC File No. 112 3095.

XIII.

IT IS FURTHER ORDERED that respondent GeneLink, Inc., and its successors and assigns, within sixty (60) days after service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

XIV.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this _____ day of August, 2013.

GENELINK, INC.

By: _____ Date:_____
BERNARD L. KASTEN, JR., M.D.
Chief Executive Officer

By: _____ Date:_____
JEANNIE M. PERRON, ESQ., D.V.M.
Covington & Burling LLP
Counsel for GeneLink, Inc.

_____ Date: _____
CAROLYN L. HANN
LAURA RIPOSO VANDRUFF
MARY L. JOHNSON
KEITH FENTONMILLER
Counsel for the Federal Trade Commission

APPROVED:

_____ Date: _____
MARY K. ENGLE
Associate Director
Division of Advertising Practices

_____ Date: _____
MANEESHA MITHAL
Associate Director
Division of Privacy and Identity Protection

_____ Date: _____
JESSICA L. RICH
Director
Bureau of Consumer Protection