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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
	)	DOCKET NO. C-4456
GENELINK, INC., a corporation, also d/b/a GENELINK BIOSCIENCES, INC.	)	DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 et seq.; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order ("consent agreement"), which includes: a statement by the respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the consent agreement, and only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

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

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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.

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, and 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, and 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 itsaffiliates' representations and disclosures to ensure compliance with Parts I through IIIbf this order. The system shall be implemented as follows:

1. No later than thirty (30) days after the date of service of 2(o)-4(l)-6(atT)-6(er)-1(t)

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

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 VII 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, Bureaiaiaia5 Td [(((tif)5(ie)64(ha)46(en)-s)-5(t)e;tcionacth cd(a) tm

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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., 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 on