

Complaint

IN THE MATTER OF

GENELINK, INC.
D/B/A
GENELINK BIOSCIENCES, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4456; File No. 112 3095*
Complaint, May 8, 2014 – Decision, May 8, 2014

This consent order addresses GeneLink, Inc., also doing business as GeneLink Biosciences, Inc.'s advertising and promotion of purported genetically customized nutritional supplements and skin repair serum products sold through a multi-level marketing network. The complaint alleges that GeneLink 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 further alleges 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. Additionally, the complaint alleges that GeneLink failed to provide reasonable and appropriate security for consumers' personal information. 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 order also 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 respondent relies 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.

Participants

For the Commission: *Megan Cox, Keith Fentonmiller, Carolyn L. Hann, Mary L. Johnson, and Laura Riposo VanDruff.*

For the Respondent: *John Graubert and Jeannie Perron, Covington & Burling LLP.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that GeneLink, Inc., a corporation, and foruTM International Corporation, formerly known as GeneWize Life Sciences, Inc. (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent GeneLink, Inc. (“GeneLink”), also doing business as GeneLink Biosciences, Inc., is a publicly held Pennsylvania corporation with its principal office or place of business at 8250 Exchange Drive, Suite 120, Orlando, Florida 32809.

2. Respondent foruTM International Corporation (“foruTM”), formerly known as GeneWize Life Sciences, Inc., is a Delaware corporation with its principal office or place of business at 1231 Greenway Drive, Suite 200, Irving, Texas 75038.

3. Respondents have developed, advertised, labeled, offered for sale, and sold through a multi-level marketing system utilizing affiliates and licensees, nutritional supplements and skincare products, including a line of customized products sold under several names such as LifeMap ME DNA Customized Nutritional Supplements, GeneWize Customized Nutritional Supplements, LifeMap ME DNA Customized Skin Repair Serum, and GeneWize Customized Skin Repair Serum.

4. Respondents purport to customize their nutritional supplements and skincare products to each consumer’s genetic disadvantages. Using an “at home” cheek swab kit, each consumer submits a cheek swab to respondents. Respondents then send the swab sample to a third-party laboratory for analysis of genetic variations called single nucleotide polymorphisms (“SNPs”). Based on the laboratory test results, respondents prepare a DNA assessment that recommends specific levels of nutritional support based on each SNP analyzed.

5. Respondents’ LifeMap Healthy Aging Assessment analyzes 12 SNPs that purportedly affect nutritional health and

Complaint

aging, and their LifeMap Skin Health Assessment, formerly known as the Dermagenetic SNP Assessment, analyzes six SNPs that purportedly affect skin health and aging (collectively, “DNA Assessments”). According to respondents, each SNP “predicts biochemical processes that are associated with significant physiological disadvantages, . . . the negative potential [of which] has been scientifically proven to be modulated by nutritional supplementation.” Compl. Ex. A.

6. Based on the DNA Assessments, respondents offer dietary supplements and skincare products that are purportedly customized to each consumer’s unique genetic profile.

7. In their business practices, respondents obtain consumers’ genetic information. Since 2008, respondents have collected genetic information from nearly 30,000 consumers.

8. Respondents’ nutritional supplements are “drugs” or “food” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act (“FTC Act”).

9. Respondents’ skincare products are “drugs” or “cosmetics” within the meaning of Sections 12 and 15 of the FTC Act.

10. The acts and practices of respondents, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.

Advertising and Marketing

11. Respondents have developed and disseminated or caused to be disseminated advertisements, packaging, and promotional materials for respondents’ genetically customized nutritional supplements and skincare products including, but not limited to, Exhibits A through I. These materials contain the following statements and depictions:

Complaint

A. LifeMap ME DNA Customized Nutritional Supplement Pamphlet (Ex. A)

Healthy Aging is Now as Close as Your **DNA!**
Genetically Customized Nutritional Supplements
Made Exclusively for You.

* * *

Why These Aging Genes?

Although human DNA contains several million natural genetic variations (called SNPs), GeneLink scientists used the following criteria to choose the SNPs for the GeneWize Healthy Aging DNA Assessment:

1. **Valid:** The existence of the SNP is supported by solid, credible, scientific evidence.
2. **Important:** A SNP predicts biochemical processes that are associated with significant physiological disadvantages.
3. **Frequent:** [T]he SNP is relatively common among the general population.
4. **Actionable:** A SNP's negative potential has been scientifically proven to be modulated by nutritional supplementation.

B. The New Wellness Frontier Brochure (Ex. B)

By analyzing and understanding your unique genetic strengths and weaknesses, you can eliminate the guesswork and “genetically guide” the optimal nutritional supplement or skincare formulation to match your LifeMap Healthy Aging Assessment™.

. . . Research shows that we can measure SNPs and have the ability to impact the expression of our genes through proper nutritional support.

* * *

Complaint

What will I feel after taking my LifeMap ME Formula?

Since everyone's body is different, you'll likely receive unique benefits from your product. Some of the benefits you may notice and some you may not. Some of the most common benefits people report include:

- Ability to fall asleep faster
- Longer, deeper sleep . . .

You may or may not experience these same results. Your body is unique and so is your formula. It makes sense that your results will be unique too.

C. Your Genetic Compass Brochure (Ex. C)**GENETICALLY GUIDED PERSONALIZATION OF NUTRIENT AND SKIN CARE FORMULATIONS.**

The Nutragenetic and Dermagenetic SNP assessments [i.e., the DNA Assessments] examine a variety of genes which are responsible for making proteins that play a very important role in our overall health. These include oxidative stress, heart and circulatory health, immune health, bone health, pulmonary [sic] health, eye/vision health, defense against environmental pollutants, collagen breakdown, photoaging, skin slacking & wrinkling and mild irritation.

KEY POINT *If the Nutragenetic and Dermagenetic SNP test predicts that you might not be as efficient as possible in any given health area, you may be able to do something about it. For every SNP tested, there are potentially compensating and enhancing nutrients that can put you on a better path toward optimal health.*

* * *

There are millions of SNPs. However, only certain subsets are associated with increased risk for disease

Complaint

and physiologic health conditions. . . . GeneLink selects only those SNPs which can be addressed using nutrients or formulations or lifestyle modifications.

D. Welcome to genewize [sic]: Making Wellness Personal Brochure (Ex. D)

What Are Your Options to Improve Health and Wellbeing?

- Eating healthier?
- Pharmaceuticals?
- Exercise?
- Guessing at supplements?
- Genetically guided nutrition!

Do you have a plan to capitalize on this new science?

* * *

GeneWize . . . Connecting the Dots

- Over 14 Years R&D Prior To Launch
- Developed significant DNA tests for SNPs on “Heavy Lifters”
- Developed “SNP Boosts” to mitigate, compensate, or bypass SNP effects
- Powerful health and wellness benefits!

ONLY comprehensive genetically guided products!

A View Into Your Patient or Customer . . .

- Patented DNA Collection Kit
- Sophisticated Assessment
- Confidentiality
- Pinpoint Genetic Predispositions
- Personalized Formula

Complaint

Over 500,000 Possibilities**With a simple cheek swab**

We Assess . . . Others Guess . . .

**E. Cover Letter to GeneWize Fulfillment Package
(Ex. E)****LifeMap Essentials™**

Your Foundation for Optimal Wellness

Welcome and congratulations for taking an important next step toward healthy aging with the most advanced and scientifically proven nutritional supplement programs available – the **LifeMap Nutrition™ System**, which consists of the following:

1. The **LifeMap DNA collection kit** (provided by GeneLink, Inc.)
2. The **LifeMap Essentials™** formula (A non-custom foundation supplement to be taken while awaiting your Healthy Aging Report & DNA guided LifeMap Custom formula)
3. The **LifeMap DNA Healthy Aging Report™** (results in about 4 weeks after mailing your DNA collection kit)
4. The **LifeMap Custom™** formula (A totally customized formula based on your DNA)

**F. GeneWize Official Website, mygenewize.com
(Ex. F)**

LifeMap Nutrition™ System Testimonials

Seeing is believing but I can't believe what [I] am seeing!

. . . [T]he best of all is the lack of pain on my knees and hips when running. Running was my passion but severe knee and hip pain kept me from it the last 10

Complaint

years. LifeMap is renewing me in ways I never thought possible. . . .

Loving life, Margarita Nido Stewart

* * *

GeneWize has changed my health and my life!

I'm in my 5th month on the LifeMap Custom supplements and I'm amazed by my personal results. So far I've experienced great sleep, great energy, great skin, and much more. Plus, I continually notice even more positive changes: prior to taking the LifeMap supplements, my memory wasn't the greatest – but now I feel much sharper mentally! This is very important to me because my Mother had Alzheimer's. . . .

Roberta Johnson, GeneWize Affiliate, Miami, Florida

* * *

Thanks for the Memories

. . . I do have certain health challenges and when I started taking my LifeMap Product, after about a week and a half I was amazed to feel tremendous results! Before, I was getting only about three hours of sleep, now I can finally sleep! My concentration & memory also seem to be improving! . . .

Lina M. Oliver

* * *

LifeMap Nutrition Meets Karaoke!

After taking the LifeMap Product for only two weeks I have a lot more energy and my dry skin has improved dramatically. . . . I also began to see something amazing happen: I went from getting very little sleep

Complaint

at night to now sleeping like a baby! I've been waking up feeling so refreshed that I want to jump up and down on my bed like a child I'm feeling so happy I've been out singing Karaoke and having a blast.

You couldn't pay me to stop taking the LifeMap Nutrition™. I have the energy to pursue my dreams of being a singer, and much more! . . .

Talina Oblander

* * *

Wife Says, "Send me my LifeMap Nutrition too."

I have been taking the LifeMap Nutrition™ supplement now for two months.

Although I wanted my wife to try the program too, she just wouldn't budge. She said she'd have to wait to see how I felt first. Well, I'm now sleeping through the night for the first time in twelve years. . . .

Ernest Smith

* * *

Another Sleep Story. It's Making Us Sleepy

I've always had a problem with sleeping through the night. Within two days of taking the LifeMap product I immediately noticed I was finding the special peace a full seven to eight hours of sleep offers. Problem solved! GeneWize has revolutionized my life and I bless all the company every day for it's [sic] incredible science. . . .

Kent Riedesel

Complaint

G. GeneWize e-lift newsletter: Monthly E-News Exclusively for GeneWize Affiliates (Ex. G)

Spotlighting Top Leader
Chief Alexander Taku:
My Visionary Source Of Success In GeneWize

. . . I decided to enroll in GeneWize and know my DNA . . . six months ago. . . . My health condition prior to this occasion was life-threatening. . . . I was a serious diabetic and cardiac patient. . . . One would never have imagined . . . that a company would come up with free DNA assessments for all! . . . Six months on the products has produced wonderful results. My blood sugar has stabilized at 80/130 and my diabetic problem is over, while a recent medical report has revealed the reduction of my heart to normal size. . . . For the last six months, I have only been taking my free GeneWize nutritional supplements. . . .

H. GeneWize Affiliate Website, thegenecollective.com (Ex. H)

Zero limits
Gene Team

* * *

I've been fielding a lot of questions about just what Genewize [sic] has done for people.

I myself can report deeper sleep and healthier feeling skin. I've talked with a number of people who have experienced improvements in everything from blood pressure to eczema to hormonal issues to arthritis. The most common observations people note are better sleep and improved energy levels. . .

* * *

I am a Massage Therapist and have had tremendous pain and stiffness in the morning after doing too many

Complaint

massages for the last few years. I used to take Glucosamine, which did seem to help with the pain and stiffness, but it wasn't total relief. After taking the LifeMap product it hit me one day that I was no longer in pain when I woke in the morning, and the stiffness had disappeared. You see, my Genetic Assessment Report had found that I need maximum support for the cartilage [sic] in my body. Mystery solved!

Warm Regards, A.R., LMP

* * *

. . . [T]he best of all is the [sic] lack of pain on my knees and hips when running. Running was my passion but severe knee and hip pain kept me from it the last 10 years. LifeMap is renewing me in ways I never thought possible. ?? [sic] Thank you to all those behind the GeneWize Lifemap [sic] NutritionTM System . . . Now, can you imagine what LifeMap is doing to what we can't see!!!

Loving life, M.N.S.

I. LifeMap ME DNA Skin Repair Serum Pamphlet (Ex. I)

Historic Evolution in Skin Care
Genetically Customized Skin Care Made Exclusively for You.

* * *

What Do Your Genes Know That You Don't?

DNA profiling revolutionized the legal world, and now it's doing the same for skin care. Now the same technology can be used to identify a whole new set of perpetrators. The main suspects? Collagen breakdown, sun damage, sensitivity, and oxidative

Complaint

stress caused by free radical activity due to environmental pollution [sic].

So how do you know how susceptible you are to these aging culprits?

Take a minute to swab inside your cheek. Place your DNA sample inside our bar-coded envelope, and send to our lab. We assess six skin health genes to tell you what skin aging problems you're likely to face as you age.

The information is then used to customize a skin repair serum using a combination of active ingredients selected to compensate for particular deficiencies in areas of skin aging, wrinkling, collagen breakdown, irritation and the skin's ability to defend against environmental stresses.

* * *

How Does it Work?

* * *

The patented, non-invasive simple swab allows you to peek into your predispositions to discover what your genes have to say about your skin aging future.

* * *

Clinically Proven Results

An eight-week, double blind, randomized and controlled clinical study compared the performance of placebo skin care versus the performance of the "genetically-customized" skin care formula containing active ingredients designed for each participant. For those using the genetically-customized formulation, 62% reported substantial reduction in the appearance of wrinkles after 14 days of treatment. After 56 days, the number of participants reporting reduction in the appearance of wrinkles rose to 70%. Similarly, after

Complaint

14 days, 56% of the participants indicated improved skin firmness and after eight weeks of treatment those with improvements in skin firmness rose to 70%.

* * *

LifeMap ME DNA Skin Repair Ingredient List

Thanks to the custom nature of our product, the ingredient list will represent the latest breakthrough ingredients which have been clinically proven to enhance or diminish aging predispositions.

12. Through the means described in Paragraph 11, respondents have represented, expressly or by implication, that genetic disadvantages identified through respondents' DNA Assessments are scientifically proven to be mitigated or compensated for with nutritional supplementation.

13. In truth and in fact, genetic disadvantages identified through respondents' DNA Assessments are not scientifically proven to be mitigated or compensated for with nutritional supplementation. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

14. Through the means described in Paragraph 11, respondents have represented, expressly or by implication, that their custom-blended nutritional supplements effectively compensate for genetic disadvantages identified by respondents' DNA Assessments, thereby reducing an individual's risk of impaired health or illness.

15. Through the means described in Paragraph 11, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 14 at the time the representation was made.

16. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 14, at the time the representation was made.

Complaint

Therefore, the representation set forth in Paragraph 15 was, and is, false or misleading.

17. Through the use of testimonials, as described in Paragraph 11, respondents have represented, expressly or by implication, that their custom-blended nutritional supplements treat or mitigate diabetes, heart disease, arthritis, and insomnia, among other ailments.

18. Through the means described in Paragraph 11, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 17 at the time the representations were made.

19. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 17, at the time the representations were made. Therefore, the representation set forth in Paragraph 18 was, and is, false or misleading.

20. Through the means described in Paragraph 11, including, but not necessarily limited to, the statements and depictions contained in the materials attached as Exhibit I, respondents have represented, expressly or by implication, that their genetically customized skin repair serum is scientifically proven to: (a) reduce the appearance of wrinkles and improve skin firmness; and (b) enhance or diminish aging predispositions, including collagen breakdown, sun damage, and oxidative stress.

21. In truth and in fact, respondents' genetically customized skin repair serum is not scientifically proven to: (a) reduce the appearance of wrinkles and improve skin firmness; or (b) enhance or diminish aging predispositions, including collagen breakdown, sun damage, and oxidative stress. Therefore, the representations set forth in Paragraph 20 were, and are, false or misleading.

22. Respondents have provided advertisements and promotional materials to affiliates for use in their marketing and sale of respondents' genetically customized nutritional

Complaint

supplements and skincare products, including the attached Exhibits A and G.

23. Through the means described in Paragraph 22, respondents have provided means and instrumentalities to respondents' affiliates in furtherance of the deceptive and misleading acts or practices alleged in Paragraphs 12 through 21.

Data Security

24. Through sales of purported genetically customized nutritional supplements and skincare products, respondents obtain consumers' personal information, including, but not limited to, consumers' names, addresses, email addresses, telephone numbers, dates of birth, Social Security numbers, bank account numbers, credit card account numbers, and genetic information.

25. Respondents use third parties to receive, process, or maintain this personal information ("service providers"), and respondents store consumers' personal information on their corporate network.

26. Respondents permit service providers to access consumers' personal information so that service providers may, among other services, develop and maintain respondents' customer relationship management database, fulfill customers' orders, and develop related applications.

27. Misuse of the types of personal information respondents collect – including Social Security numbers, dates of birth, and genetic information – can facilitate identity theft, privacy harms, and other consumer injuries.

28. Since at least November 2008, respondents have disseminated or caused to be disseminated to consumers privacy policies and statements, including, but not limited to, a Privacy Protection Policy (Exhibit J). This policy contains the following statements:

Complaint

GeneWize Life Sciences, Inc. Privacy Protection Policy (Exhibit J)

GeneWize Life Sciences respects the privacy of every individual and has taken every precaution to create a process that allows individuals to maintain the highest level of privacy. All information provided by the individual taking the assessment is kept on a secure server

* * *

We send Personal Customer Information to third-party subcontractors and agents that work on our behalf to provide certain services. These third parties do not have the right to use the Personal Customer Information beyond what is necessary to assist us or fulfill your order. They are contractually obligated to maintain the confidentiality and security of the Personal Customer Information and are restricted from using such information in any way not expressly authorized by GENEWIZE.

29. Respondents have engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for consumers' personal information. Among other things, respondents:

- a. Failed to implement reasonable policies and procedures to protect the security of consumers' personal information collected and maintained by respondents;
- b. Failed to require by contract that service providers implement and maintain appropriate safeguards for consumers' personal information;
- c. Failed to provide reasonable oversight of service providers, for instance by requiring that service providers implement simple, low-cost, and readily

Complaint

available defenses to protect consumers' personal information;

- d. Created unnecessary risks to personal information by:
 - i. maintaining consumers' personal information, including consumers' names, addresses, email addresses, telephone numbers, dates of birth, Social Security numbers, and bank account numbers, in clear text;
 - ii. providing respondents' employees, regardless of business need, with access to consumers' complete personal information;
 - iii. providing service providers with access to consumers' complete personal information, rather than, for example, to fictitious data sets, to develop new applications;
 - iv. failing to perform assessments to identify reasonably foreseeable risks to the security, integrity, and confidentiality of consumers' personal information on respondents' network; and
 - v. providing a service provider that needed only certain categories of information for its business purposes with access to consumers' complete personal information; and
- e. Did not use readily available security measures to limit wireless access to their network.

30. In March 2012, 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 foruTM (then known as GeneWize) customer and affiliate in respondents' customer relationship management database. The personal information that could have been accessed

Complaint

included consumers' names, addresses, email addresses, telephone numbers, dates of birth, and Social Security numbers.

31. Through the means described in Paragraph 28, respondents have represented, expressly or by implication, that they implement reasonable and appropriate measures to secure consumers' personal information.

32. In truth and in fact, as set forth in Paragraph 29, respondents have not implemented reasonable and appropriate measures to protect consumers' personal information from unauthorized access. Therefore, the representation set forth in Paragraph 31 was, and is, false or misleading.

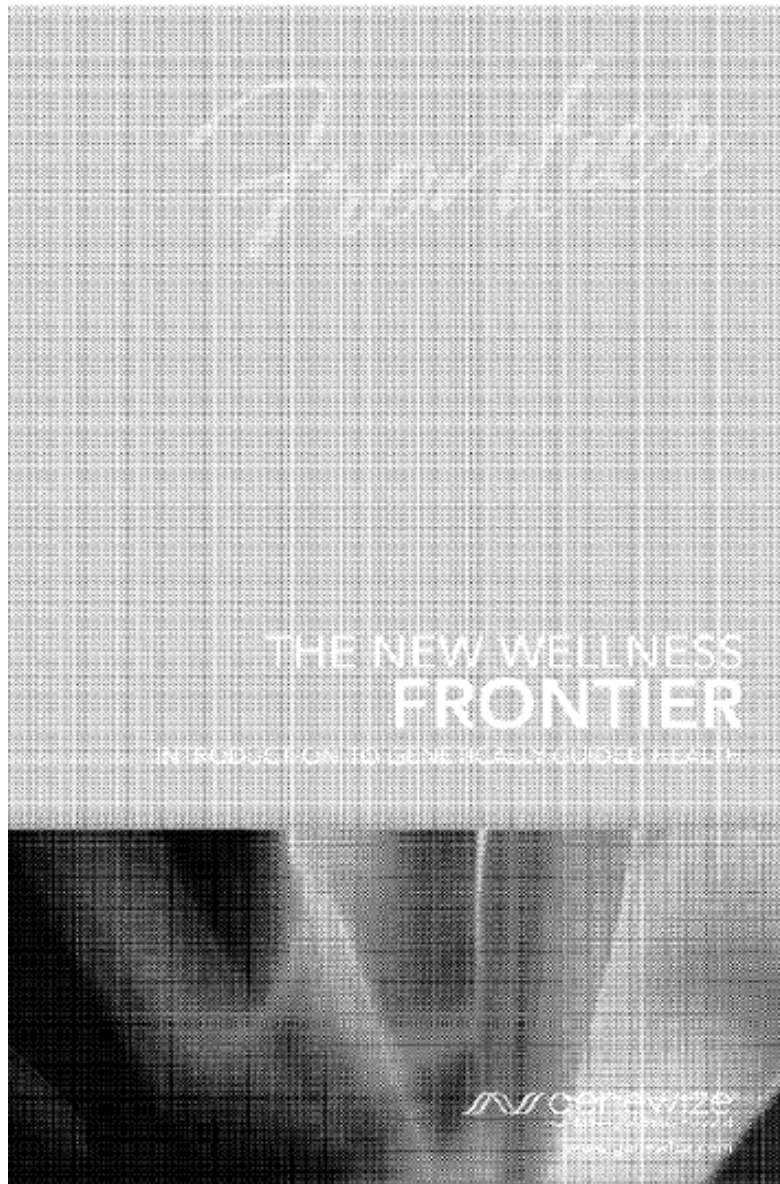
33. As set forth in Paragraph 29, respondents failed to employ reasonable and appropriate measures to prevent unauthorized access to consumers' personal information. Respondents' practices are likely to cause substantial injury to consumers that is not reasonably avoidable by consumers themselves and is not outweighed by countervailing benefits to consumers or competition. This practice was, and is, an unfair act or practice.

34. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act.

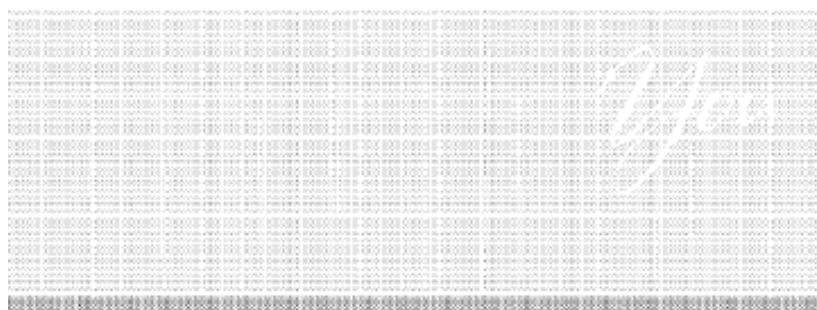
THEREFORE, the Federal Trade Commission, this eighth day of May, 2014, has issued this complaint against respondents.

By the Commission, Commissioner Ohlhausen dissenting, and Commissioner McSweeney not participating.

Complaint

Exhibit B**Exhibit B**

Complaint



GENETICS AND PERSONALIZED HEALTH

Recently, scientists have confirmed that each of us has unique, "genetically determined" body chemistries.

Even small variations in your genes can have a significant influence on how well your body responds to food, nutrients, physical activity, environmental stresses and how you may be predisposed to a variety of other important health and physiological conditions.

By analyzing and understanding your unique genetic strengths and weaknesses, you can eliminate the guesswork and "genetically guide" the optimal nutritional supplement or skincare formulation to match your LifeMap Healthy Aging Assessment®.

This is a revolutionary new scientific approach to delivering formulations that fulfill INDIV DUAL needs, based on confidential genetic testing.

GENETICS TUTORIAL

Within every human cell is an individual's blueprint for life—their DNA. DNA contains the master information that is needed to construct and maintain the human body.

SMALL CHANGES IN DNA THAT IMPACT OUR PHYSIOLOGY

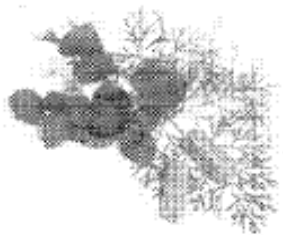
On a strictly DNA basis, humans are surprisingly alike. Despite our apparent differences, the DNA between any two people is 99.1% identical. That 0.9% variation in DNA, however, is hugely important, accounting for most of our physical differences.

Small variations in DNA are called polymorphisms. Skin type is a common human polymorphism. Depending on the order in which the nucleotides in your DNA line up, you could have different skin. Some polymorphisms are so small, they affect the order of just one pair of nucleotides. These are called single nucleotide polymorphisms or SNPs (pronounced "snips"). Research shows that we can measure SNPs and have the ability to impact the expression of our genes through proper nutritional support.



Exhibit B

Complaint


**THE LIFEMAP NUTRITION™
SYSTEM HAS THESE FEATURES:**

- » Pharmaceutical grade manufacturing
- » Significant antioxidant support
- » Whole foods
- » Organic ingredients
- » 5,000 to 9,000 ORAC units
- » Includes Cat's Claw for its antioxidant activity.
- » Less caffeine than 1/4 cup of coffee
- » Affordable at about \$3/day

**ENVIRONMENTALLY FRIENDLY,
SOCIAALLY RESPONSIBLE
PACKAGING**

GeneWise is an environment-friendly company. Here are some ways we deliver socially responsible nutrition.

- » Recycled packaging
- » No plastic bottles or boxes
- » Reusable daily pouches
- » Vegetable-based capsules
- » No animal products or testing

COMMON QUESTIONS...
Do I need to take my other supplements?

The LifeMap Nutrition™ System will in many cases replace most multivitamins you are taking and your formula is so rich in antioxidants, you may be able to replace those supplements too. Certain supplements may not be available in the LifeMap Nutrition™ System.

What do you do with my DNA and how do you protect my privacy?

Your privacy is very important to us. We protect you by sending your DNA to our lab with only a bar code so your name is not identified with the sample. Once the analysis is completed your DNA is destroyed and your results are sent to our secure database to create your personalized supplement.

What will I feel after taking my LifeMap *me* Formula?

Since everyone's body is different, you'll likely receive unique benefits from your product.

Some of the benefits you may notice and some you may not. Some of the most common benefits people report include:

- » Ability to fall asleep faster
- » Longer, deeper sleep
- » More energy during the day
- » Softer skin
- » Stronger hair and nails

You may or may not experience these same results. Your body is unique and so is your formula. It makes sense that your results will be unique too.

Exhibit B

Complaint

Exhibit C



Exhibit C

C

Complaint



THE NEW SCIENCE OF NUTRAGENETICS AND DERMAGENETICS

Nutrigenetics and Dermagenetics are a combination of the sciences of genetics, nutrition and skin care that reveal personalized information regarding an individual's status and provides the basis for selecting a dietary, nutritional and skin care program best suited to achieving the healthiest and longest life possible.

- Nutrigenetics and Dermagenetics use SNP testing to identify areas of an individual's genetic make-up that may be functioning less than optimally.
- Nutrigenetics and Dermagenetics can help guide individuals in choosing the optimal combination of nutrients and vitamins and topical active ingredients matched to their unique genetic make-up.

For the first time, this revolutionary SNP science is making it possible to personalize and tailor health and skin care products. How is this done?

GENETICALLY GUIDED PERSONALIZATION OF NUTRIENT AND SKIN CARE FORMULATIONS.

The Nutrigenetic and Dermagenetic SNP assessments examine a variety of genes which are responsible for making proteins that play a very important role in our overall health. These include oxidative stress, heart

and circulatory health, immune health, bone health, pulmonary health, eye/vision health, defense against environmental pollutants, collagen breakdown, photoaging, skin slacking & wrinkling and mild irritation.

KEY POINT *If the Nutrigenetic and Dermagenetic SNP test predicts that you might not be as efficient as possible in any given health area, you may be able to do something about it. For every SNP tested, there are potentially compensating and enhancing nutrients that can put you on a better path toward optimal health.*

KEY POINT *Due to our busy lifestyles and environmental exposure, most people don't have enough time in everyday life for 5-6 servings of fruits and vegetables as well as a total skin care regime. It is logical then that most everyone should use a basic multivitamin and mineral formulation as well as base topical skin care formulation to cover the major areas of general nutrition and skin fitness, and add additional ingredients based upon your personal genetic SNP test results.*

Complaint

GeneLink's statistical results demonstrate that virtually everyone tested will require Added Support and/or Maximum Support in at least one or two gene SNP areas.

Why are the SNPs used in GeneLink's profiles selected over millions of others?

There are millions of SNPs. However, only certain subsets are associated with increased risk for disease and physiologic health conditions.

GeneLink selects only 'functional SNPs' which indicate poor enzyme function via epidemiological or biochemical studies.

Additionally, GeneLink selects only those SNPs which can be addressed using nutrients or formulations or lifestyle modifications.

These SNPs physically reside in either the coding region (protein portion) of the gene which can alter enzyme function or they reside in the promoter region which affects the level of expression of the gene in question.

What is the clinical research that ties nutritional supplements and topical skin treatments to support SNP predispositions?

All of the enzymes represented in the SNP profile have been well-studied and there is biochemical evidence in almost every instance that correlates why an enzyme affected by the SNP does not function properly. Additionally, there is leading clinical evidence linking SNPs to nutrition.

Thus, for major enzymatic players of oxidative stress, there is a clear fit with the genetics, epidemiology and biochemistry.

For several of the SNPs, there is a direct link between having the SNP and being able to lower oxidative stress or the potential health risks associated with oxidative stress by the

ingestion or application of particular antioxidant nutrients and active ingredients.

For example the SNP for methylenetetrahydrofolate reductase (MTHFR or Heart, Circulatory Health-2), produces an enzyme with decreased affinity (Km) for its direct substrate, 5,10 methylene-THF, which can cause a build up of homocysteine, which is deleterious to heart health. Increasing folic acid (upstream substrate) or the product of the enzyme reaction (5 methyl-THF) can ameliorate the build-up of homocysteine.

For some SNPs there is no definitive clinical evidence available to date that directly links the benefit of a nutrient to the SNP. These studies will come in time. Nevertheless, the fact that the biochemical parameters for all of the SNPs are so well known provides a rational nutritional approach to addressing unfavorable physiological conditions, based on scientific knowledge of how the SNP specifically functions.

Who conducted the research and who endorses GeneLink's research?

GeneLink's medical and scientific advisors along with independent academic laboratories and medical centers have conducted nearly 100% of the work. GeneLink's medical and scientific advisors hold positions at major research institutions.

The science and technical information behind GeneLink's technology has been favorably reviewed by the scientific staff department of our various clients and collaborative partners.

Studies have been statistically quantified and involve sophisticated molecular biology, biochemistry and genetic analysis.



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Exhibit C

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Exhibit D**Exhibit D**GNLK015269
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What Are Your Options To Improve Health and Wellbeing?

- Eating healthier?
- Pharmaceuticals?
- Exercise?
- Guessing at supplements?
- Genetically guided nutrition!

Do you have a plan to capitalize on this new science?



Exhibit D

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GeneWize...Connecting the Dots

- Over 14 Years R&D Prior To Launch
- Developed significant DNA tests for SNPs on “Heavy Lifters”
- Developed “SNP Boosts” to mitigate, compensate, or bypass SNP effects
- Powerful health and wellness benefits!

***ONLY* comprehensive
genetically guided
products!**



Exhibit D

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A View Into Your Patient or Customer...

- Patented DNA Collection Kit
- Sophisticated Assessment
- Confidentiality
- Pinpoint Genetic Predispositions
- Personalized Formula

**Over 500,000
Possibilities**

With a simple cheek swab...



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We Assess...Others Guess

Targeted Genes Include:

- Oxidative Stress
- Detoxification & Environmental Challenges
- Cardiovascular Health
- Breast and Lung Tissue
- Immune Health
- Neurological Health
- Pulmonary Health
- Eye/Vision Health
- Collagen
- CoQ10
- Bone

Custom Is Better

Healthy Aging DNA Assessment results support level

One disadvantaged gene SNP from one of six panels at this personal health area. A WELL result (Heterozygous Positive) indicates that you have one variant SNP and that the protein molecule expressing a specific enzyme, hormone, cytokine or structural protein is functioning less than optimally. ADDED SUPPORT	Two disadvantaged gene SNPs from one of six panels at this personal health area. A WELL result (Heterozygous Positive) indicates that you have one variant SNP and that the protein molecule expressing a specific enzyme, hormone, cytokine or structural protein is functioning less than optimally. ADDED SUPPORT	Three disadvantaged gene SNPs from one of six panels at this personal health area. A WELL result (Heterozygous Positive) indicates that you have one variant SNP and that the protein molecule expressing a specific enzyme, hormone, cytokine or structural protein is functioning less than optimally. ADDED SUPPORT
ADDED SUPPORT	ADDED SUPPORT	ADDED SUPPORT

Exhibit D

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Exhibit E

LifeMap Essentials™
Your Foundation for Optimal Wellness

Welcome and congratulations for taking an important next step toward healthy aging with the most advanced and scientifically proven nutritional supplement programs available – the **LifeMap Nutrition™ System**, which consists of the following:

1. The **LifeMap DNA collection kit** (provided by GeneLink, Inc.)
2. The **LifeMap Essentials™** formula (A non-custom foundation supplement to be taken while awaiting your Healthy Aging Report & DNA guided LifeMap Custom formula)
3. The **LifeMap DNA Healthy Aging Report™** (results in about 4 weeks after mailing your DNA collection kit)
4. The **LifeMap Custom™** formula (A totally customized formula based on your DNA)

Your LifeMap Essentials™ formula is the cornerstone of the LifeMap Nutrition System and forms the 'base foundation' for every individually customized LifeMap Custom product.

LifeMap Essentials is a premium plant based formula, carefully designed to provide the "key essentials" of a proper diet and to help you prepare and maintain optimal nutritional support while you are awaiting the results of your LifeMap Healthy Aging DNA Assessment and your personal DNA-guided LifeMap Custom formula (Please note: the processing time for your DNA assessment & LifeMap Custom formula is about 4 to 8 weeks from the time you mail back your DNA collection kit).

It contains a generous selection of fruits and vegetable powders with the highest phytonutrient content along with important anti-aging "superfruit" extracts such as the Brazilian acai berry, the Himalayan goji berry and the Southeast Asian mangosteen. In addition, your Essentials formula also contains a comprehensive vitamin blend, flax seeds (a source of omega-3 fatty acids) and fructooligosaccharides – a natural prebiotic fiber that promotes enhanced intestinal health for optimal nutrient absorption.

For antioxidant protection, **LifeMap Essentials** contains over 7500 ORAC (Oxygen Radical Absorbance Capacity) units, the equivalent ORAC value of eight (8) servings of fruits and vegetables. For even extra antioxidant protection, we've added OxyPhyte® Ultra, a proprietary blend of antioxidant-rich apple, white tea and rosemary extracts which has proven bioavailability in human clinical studies.

For DNA repair, we've included 350 mg of AC-11®, a patented, advanced, clinically-tested bioactive compound derived from the South American herb *Uncaria tomentosa* (Cat's Claw). AC-11® has been clinically demonstrated systemically to reduce both oxidative damage and non-oxidative damage to DNA caused by stress, viruses or bacteria as well as reduce inflammation and improve immune function in human clinical trials.

Directions for use:

Take five (5) capsules in the AM and five (5) capsules in the PM (with or without food) for a total of ten (10) capsules daily. These vegetarian capsules are specially designed that can be swallowed as you would any capsule or tablet, or if you prefer, can be broken open and mixed with your favorite juice or beverage.

We are truly grateful for you and excited to be a part of your health future.

Sincerely,
The Formulation Scientists at GeneWise Life Sciences

Exhibit E

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Complaint

Exhibit F

LifeMap Nutrition™ System Testimonials

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Genewize Life Sciences

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Testimonials
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CustomerService@genewize.com

LifeMap Nutrition™ System Testimonials

☐ **Seeing is believing but I can't believe what am seeing!**

"I was excited to learn about LifeMap Nutrition™ and now even more excited about the many changes I have experienced during the last four months of use. Although I have devoted the last twenty years to good eating and exercise, I love the fact that many that know me have been noticing improvements in my overall health and wellness appearance. I started noticing changes after two and a half weeks and they are still taking place. Hard nails and without ridges like never before, silky and soft hair, dry skin gone and now with a glow, sleeping deep without disruption like I did in my teens, waking up rested and ready to go, energy I didn't realize I could regain and the best of all is the lack of pain on my knees and hips when running. Running was my passion but severe knee and hip pain kept me from it the last 10 years. LifeMap is renewing me in ways I never thought possible.

Thank you to all those behind the Genewize LifeMap Nutrition™ System. I appreciate your devotion and determination for making a product like this. Now, can you imagine what LifeMap is doing to what we can't see!!!"

Loving life, Margarita Nido Stewart

http://web.ushnet.org/web/2009/02/20/1313/http://mygenewise.com/Testimonials.aspx?ID=www [1 of 1] [7/12/2011 6:24:30 PM]

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Exhibit F

Complaint

LifeMap NutriSense™ System Testimonials

George Muresan

Me and My Elbow Feel Great!

George Muresan

"I always took vitamins throughout my NBA Career. After an injury in 1998, my doctor gave me even more vitamins and minerals to take but I got very sick after taking them. I called the doctor, but he couldn't suggest anything other than to tell me to keep on taking the vitamins. I kept on feeling so sick that I decided just to stop taking supplements at all. When I was first introduced to GeneWise in 2008 I was very skeptical, but I decided to give it a try. After about a week of being on the LifeMap NutriSense™ a continual discomfort in my right elbow subsided. I also found I could sleep through the night again and my energy improved. I've been taking the LifeMap Supplements for several months now and just feel great."

Gheorghe Muresan, Former NBA Player

**Partnering with Your Body:
Dialing it in by "Assessing, not Guessing"**

"I have been supplementing for years as I have always believed it is necessary for me to partner with my body so it can care for itself and give it all the advantages necessary to maintain health and balance. I have always thought supplements were just that - a way to get my body what it needs so it can do its job. Once I looked through my assessment, I found that I was taking some supplements that I really didn't need and NOT taking ones I did need. The time, effort and money that the LifeMap customized supplement saves me every month is staggering. To try and put a product like this together on my own would cost a fortune and honestly, who has the time?"

"The results have been really substantial. I have always been a pretty good sleeper, or so I thought. The profound shift in the depth and quality of sleep I get now is amazing and I no longer have those afternoon lulls of energy. I can't imagine ever going back to generic, mass marketed off the shelf supplements. The GeneWise product is truly fantastic!"

Keith O'Brien, Independent Founding Affiliate

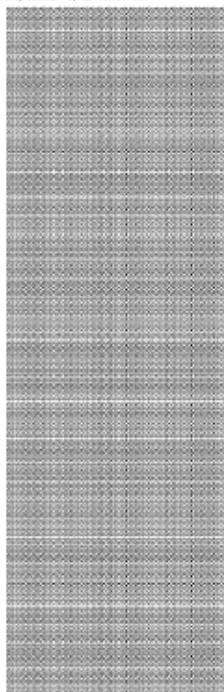
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LifeMap Nutrition™ System Testimonials

**GeneWize has changed my health and my life!**

"I'm in my 5th month on the LifeMap Custom supplements and I'm amazed by my personal results. So far I've experienced great sleep, great energy, great skin, and much more. Plus, I continually notice even more positive changes: prior to taking the LifeMap supplements, my memory wasn't the greatest - but now I feel much sharper mentally! This is very important to me because my Mother had Alzheimer's."

"The Healthy Aging DNA Assessment provided me with such valuable information. At 52, some of my assessment results weren't a surprise, but I wasn't expecting to learn I had a double SNP in my detox gene. In our toxic world, this is valuable information we could use when we're very young- the younger the better!"

"With all of great benefits I'm experiencing, I know the LifeMap Custom supplements are supplying me with the 'right fuel' and a much needed tune up! GeneWize has changed my health and my life for the better!"

Roberta Johnson, GeneWize Affiliate, Miami, Florida

How To Get the LifeMap Edge

King Minor

"Taking care of your body is essential. With GeneWize's LifeMap Nutrition™ System and products, I am not only taking care of my body, I have an edge. I feel great knowing that I am giving my body exactly what it needs."

Greg Minor
Former NBA Player for the Boston Celtics

<http://web.archive.org/web/20090220081215/http://mygenewize.com/Testimonials.aspx?ID=news-14-of-11> (7/12/2011 8:24:30 PM)

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LifeNag Sublimin® System Testimonials

Jillian Montes De Oca

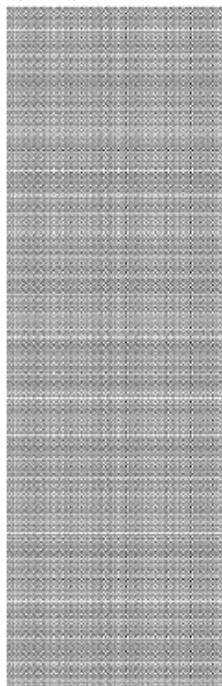
Thank you, Genewiz
Anne Zirkle

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LifeMap Nutrition™ System Testimonials

**Randy Keeps it Short and Sweet**

After taking the LifeMap Product it made me feel more energetic.

Randy Levine

Thanks for the Memories

When I received my customized report, I was very happy to see my DNA Assessment results, especially since I don't know about my parents. So in a way it was also a surprise!

I do have certain health challenges and when I started taking my LifeMap Product, after about a week and a half I was amazed to feel tremendous results! Before, I was getting only about three hours of sleep, now I can finally sleep! My concentration & memory also seem to be improving!

Thanks to all the scientists and doctors that made it possible!

Now is my turn to help people with the LifeMap Nutrition™ Product!

Lisa M. Oliver

LifeMap Nutrition Meets Karaoke!

After taking the LifeMap Product for only two weeks I have a lot more energy and my dry skin has improved dramatically. (I noticed these changes within two weeks). I also began to see something amazing happen: I went from getting very little sleep at night to now sleeping like a baby! I've been waking up feeling so refreshed that I want to jump up and down on my bed like a child (I am 27 years old). I'm feeling so happy I've been out singing Karaoke and having a blast.

You couldn't pay me to stop taking the LifeMap Nutrition™. I have the energy to pursue my dreams of being a singer, and much more!

I can't THANK YOU enough GeneWise.

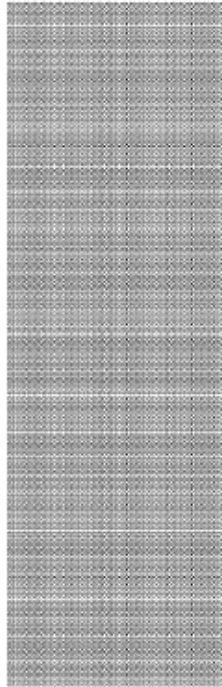
I LOVE YOU! XOXO

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Complaint

LifeMap Nutrition™ System Testimonials



Talline Oldender

Wife Says, "Send me my LifeMap Nutrition too."

I have been taking the LifeMap Nutrition™ supplement now for two months.

Although I wanted my wife to try the program too, she just wouldn't budge. She said she'd have to wait to see how I felt first. Well, I'm now sleeping through the night for the first time in twelve years!

Oh, by the way, my wife is now waiting to receive her own LifeMap Nutrition™.

Thank You GeneWize!

Ernest Smith

Another Sleep Story. It's Making Us Sleepy

I've always had a problem with sleeping through the night. Within two days of taking the LifeMap product I immediately noticed I was finding the special peace a full seven to eight hours of sleep offers. Problem solved! GeneWize has revolutionized my life and I bless all the company every day for its incredible science.

Warmest Regards,

Kent Riedesel

Lawn Mower Malaise

My husband and I have been taking our supplements for a month and a half now. We have both noticed differences and it is helping us in so many ways, not only nourishing our bodies and helping get rid of free radicals and all, it seems to be balancing us as well. What I mean by this is basically our moods.

http://news.ardnews.org/news/2009/02/20/01119/Help_Yourgenewize.com/Testimonials.aspx?ID=news%20of%2011%2012/0011%2024%20PM

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Exhibit F

Complaint

Exhibit G

e-lift

genewize®
Making Wellness Personal

MONTHLY E-NEWS EXCLUSIVELY FOR GENEWIZE AFFILIATES

January 2010

Only When You're Standing on Higher Ground ...can you reach out and lift others. Someone is looking to you for the vision, the belief, the plan. Use what you gain here to clarify your purpose, fire-up your passion and go all the way to the top.

Principles that Make a Difference



There are two principles that will have a major impact on your enrolling results (for both customers and Affiliates) AND will impact your overall attitude.

Taking this a step further, if you don't accept these principles, it's almost impossible to maintain a positive attitude as you build your business. I didn't invent these principles, but over time I've learned to understand and respect their power.

PRINCIPLE ONE: People need (and want) to Like and Trust You

If people don't buy you, they won't buy anything that comes out of your mouth. People must like and trust you if they are going to do business with you (as a customer or as an Affiliate). This is a life lesson – not just a business lesson.

continued on page 2

Contents	
Recognition	3
Top Trailer Tips	7
Business Updates	7
Gene SNPs	8
Sharon Tehaney	11
ShopGeneWize.com	12
Testimonials	13
Pro Website	15

Spotlighting Top Leader Chief Alexander Taku: My Visionary Source Of Success In GeneWize



As a traditional ruler, community leader and philanthropist, at the age of sixty three, I have spent over four decades of my life dealing directly with the life of others. I am an American trained political consultant, and a traditional ruler from Southern Cameroons in Central Africa. I am a community leader and a former member of Parliament in Cameroon. At the end of my studies in the United States, I worked for 19 years as Human Resources Manager at Pecten Cameroon Oil Company, a subsidiary of Shell Oil, USA. I have also served in various positions in community based organizations: as member of the Washington, D.C. Mayor Task Force for International Affairs, Co-founder and Chair of the Continental African Community-Montgomery County; Member, Ethnic Committee and the African Affairs Advisory Board, Montgomery County, Maryland.

I have also recorded 15 years of experience and leadership positions in Network Marketing, the last of which was National Director with 5 Link Enterprises. During my fifteen years in the Direct Sales Industry, I have not found any company with such a popular product which can improve the lives and health of every human being on earth.

I decided to enroll in GeneWize and know my DNA when Rob Podles presented the opportunity to me six months ago. He assured me of the possibility of processing my DNA and paying for my initial product for less than five hundred dollars. My health condition prior to this occasion was life-threatening. Like my parents and most members of my family, I was a serious diabetic and cardiac patient. My mother died of diabetes while my father died from a massive heart attack! I never dreamed of being able to get my DNA test because it was too expensive for a retired citizen like me. One would never have imagined for one moment that a company would come up with free DNA assessments for all! The next appreciation was the possibility for me to receive my products at no extra cost. Of course, I took the opportunity and immediately signed up four Affiliates and no longer had to pay a dime for my nutritional products. Six months on the products has produced wonderful results. My blood sugar has stabilized at 80/130 and my diabetic problem is over, while a recent medical report has revealed the reduction of my heart to normal size. Generally, I feel very strong. For the last six months, I have only been taking my free GeneWize nutritional supplements.

I salute the decision of the corporate management team to devote one

continued on page 2

Exhibit G

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e-lift

genewize®
Building Wealthy Peoples

January 2010

Page 2

We've heard story after story about how in some cases, Affiliates joined another Affiliate's business just by being asked. "If you're involved," they said, "let's get started."

Start being intentional about learning about other people's needs and you'll begin building a personal brand for yourself that says, "When I think of you, I think of someone that I like and respect."

If you focus on all of the little things that you can do to become more likeable and trustworthy (such as returning calls, keeping commitments, being interested in others, listening carefully, being more joyful, etc.) both your LIFE and your business will become more enjoyable AND fulfilling.

PRINCIPLE TWO: Like it or not, it's a numbers game, even IF people like and trust you.

You must understand that finding people to join your business and/or to purchase your products is a numbers game. The more people you speak to, the more you invite to your presentations the more people will join your team or purchase and experience our products. Yes, you can do a lot of things to increase your results over time, but you must accept and internalize the fact that success is a numbers game.

Before you start making calls and presentations, it's critical to recognize that not everyone will accept your invitation to learn about the products or the business. You will be turned down often, but you cannot allow those who decline your invitation to discourage you. It's absolutely vital that you maintain a positive attitude and move on to the next person.

To Your Good Health and Success



Monte Taylor
CEO GeneWize Life Sciences

Spotlighting Top Leader Chief Alexander Taku: (continued)

other issue of the Life Map News Letter as the E-lift edition, dedicated to recognizing top performers in the GeneWize community and about the tools that our organization offers to enable and sustain success and wellness in the Direct Sales Business.

I was proud and excited when I received the phone call from Rob Podles, inviting me to prepare this statement as a guest in the program. I also take this opportunity to explain how in the midst of my top leadership positions in other outfits in the Direct Sales Business, I chose GeneWize as the source of my lifetime success and legacy.

The secret of my stable road to success during my six months' affiliation with GeneWize has been hidden in my strong belief in the strength of the customized nutritional product. In fact, the scientific discovery of Human DNA, especially in Wellness, constitutes a landmark in our civilization. Luckily for me, the nutritional and skin care products manifested openly favorably on me. The DNA results clearly reflected my bill of health. The success of the product in reawakening and sharpening my genes to contain and neutralize my health problems has tremendously changed my life. My choice of GeneWize over the other direct sales businesses became obvious, especially, because, we are talking about me, you and us. This business is about our lives and life has no duplicate!!!.

The success of the products on me, coupled with the wonderful effective system placed at my disposal by the company are responsible for my ability to successfully reach out and sign-in several Affiliates in the GeneWize Wellness Empire. My enhanced ability to successfully create a favorable environment accounts for my increasing enrollment of more Affiliates to benefit from the GeneWize Revolution.

My approach has been to keep it simple. I make sure that our product speaks for itself and utilize the system to work for me. The effect of wonderful product, the excellent tools provided in my Website and the unmatched dynamic team in Customer Service, Compliance and the dynamic team of the passionate consumer-friendly Up-line have combined to begin the successful journey of transforming my mighty circle of influence into a huge success of Healthy Wealth. That is why my success cannot be attributed to me alone - it is rightly the result of the best product, the best system, and the best team in the Direct Sales Industry.

The success we are recording today in GeneWize must be rightly attributed to our founders and God's inspiration for their scientific breakthrough and the timing for us to be the standard bearers of the transformation to the Healthy Wealth that GeneWize brings to the World.

Where do I go from here with this mighty opportunity? Sky is the limit. I now feel more than twenty years younger and have begun living my dreams. I now feel, this is the time to build a legacy for my grand children my community, my tribe, my country and the world to remember me as one of those pioneer Affiliates who helped to change the world through the opportunity provided by the GeneWize Life Sciences. This way, I have paved the way for a healthy wealthy life, while helping to assure that I live on many years in health and wellness.

Chief Alexander Taku Fuasonganyi

Exhibit G

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Exhibit H

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zero limits
GENEWISE TEAM

GeneWize Opportunity Skin Repair Serum

GeneWize Testimonials

Sat, Dec 27, 2008 *Featured Article: Testimonials, Zero Limits Team*

I've been fielding a lot of questions about just what GeneWize has done for people. I myself can report deeper sleep and healthier feeling skin. I've talked with a number of people who have experienced improvements in everything from blood pressure to eczema to hormonal issues to arthritis.

The most common observations people note are better sleep and improved energy levels.

Below are a few GeneWize testimonials from people who felt compelled enough to write directly to GeneWize to relate their story:

"I am a Massage Therapist and have had tremendous pain and stiffness in the morning after doing too many massages for the last few years. I used to take Glucosamine, which did seem to help with the pain and stiffness, but it wasn't total relief. After taking the LifeMap product it hit me one day that I was no longer in pain when I woke in the morning, and the stiffness had disappeared. You see, my Genetic Assessment Report had found that I need maximum support for the cartilage in my body. Mystery solved! I can't thank the company enough - GeneWize, you've most likely prolonged my career."

Warm Regards, A.R., LMP

"I have been supplementing for years as I have always believed it is necessary for me to partner with my body so it can care for itself and give it all the advantages necessary to maintain health and balance. I have always thought supplements were just that -- a way to get my body what it needs so it can do its job. Once I looked through my assessment, I found that I was taking some supplements that I really didn't need and NOT taking ones I did need. The time, effort and money that the LifeMap customized supplement serves me every month is staggering. To try and put a product like this together on my own would cost a fortune and honestly, who has the time?"

"The results have been really substantial! I have always been a pretty good sleeper, or so I thought. The profound shift in the depth and quality of sleep I get now is amazing and I no longer have those afternoon lulls of energy. I can't imagine ever going back to generic, mass marketed off the shelf supplements. The GeneWize product is truly terrific!"

K.O. Independent Founding Affiliate

"I was excited to learn about LifeMap Nutrition and now even more excited about the many changes I have experienced during the last four months of use. Although I have devoted the last twenty years to good eating and exercise, I love the fact that many that know me have been noticing improvements in my overall health and wellness appearance. I started noticing changes after two and a half weeks and they are still taking place. Hard nails and without ridges like never before, silky and soft hair, dry skin gone and now with a glow, sleeping deep without disruption like I did in my teens, waking up rested and ready to go, energy I didn't realize I could regain and the best of all is the lack of pain on my knees and hips when running. Running was my passion but severe knee and hip pain kept me from it the last 10 years. LifeMap is renewing me in ways I never thought possible.???Thank

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FREE DOWNLOAD

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Exhibit H

Complaint

you to all those behind the GeneWise LifeMap Nutrition™ System. I appreciate your devotion and determination for making a product like this. Now, can you imagine what LifeMap is doing to what we can't see!!"

Loving life, M.N.S.

After taking the LifeMap Product for only two weeks I have a lot more energy and my dry skin has improved dramatically. (I noticed these changes within two weeks). I also began to see something amazing happen: I went from getting very little sleep at night to now sleeping like a baby! I've been waking up feeling so refreshed that I want to jump up and down on my bed like a child (I am 27 years old). I'm feeling so happy I've been out singing Karaoke and having a blast.

You couldn't pay me to stop taking the LifeMap Nutrition™. I have the energy to pursue my dreams of being a singer, and much more!

I can't THANK YOU enough GeneWise! LOVE YOU!!

XOXO T.O.

"When I received my customized Report I was surprised to see three areas where I needed additional support and four other areas that required maximum support.

"After two and one half months of taking the GeneWise supplement.....?I enjoy the feeling of vital energy from within?.....I have increased REM sleep, and the texture of my skin has noticeably changed from thin and flaky to soft and supple. My hair dresser is now texturizing (thinning) my hair..... ?It genuinely feels like my 60-year-old clock has begun to roll backwards.?I can't remember a time when I've awakened in the morning with such an influx of energy, a crystal clear mind, and an overall feeling of well being."

M.D.D.

The statements within thegenecollective.com have not been evaluated by the U.S. Food and Drug Administration. The GeneWise products and services are not intended to diagnose, treat, cure, prevent any disease, or replace the advice of any medical professional.

Popularity: 28% [?]

No related posts.

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Website

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Exhibit H

Complaint

Exhibit I

Often Asked Questions

Q: How can we be sure test results are kept private?

A: GeneWise maintains a strict confidentiality policy. All information provided is kept on a secure server and all samples are identified by a unique barcode only. Private information is never shared with third parties and all DNA samples are destroyed after genotyping.

Q: Is this product FDA approved?

A: Because your personal formula is not a pharmaceutical product that requires a prescription, it does not require FDA approval. All of the ingredients are a well established, safe, naturally occurring, safe, natural active ingredients. No artificial preservatives, parabens, or parabens are included.

Q: How long before I begin to see results?

A: Everyone is unique, however most people begin to see visible results within 2-3 weeks of regular use of the product.

Q: Why is it important to customize my product? Couldn't I receive the same formula for everyone?

A: Our formula is customized to your body's unique needs and more to not always better. Our customized formula focuses on providing maximum support to your individual skin health needs, as determined by your DNA assessment.

Key Skin Aging Genes and Proprietary Blend

Unique inherited capabilities for environmental defense and resistance to skin damage are determined by tiny differences in DNA, called SNPs (pronounced "snips"), which is the scientific abbreviation for Single Nucleotide Polymorphisms. The six "SNPs" we measure, through customized DNA assessment, are key genetic "Triggers" related to overall skin aging. These SNPs are listed below, along with our active ingredients, which have been clinically shown to enhance or diminish these aging predispositions:

SOD 2: Defends against oxidative stress by destroying superoxide free radicals.

SH-Active™: A combination of Lactobacillus, Lactin, and Phospholipids, Glycine, Olive Oil, and Vitamin E, which is known to help reduce skin aging.

GFN1: Helps against oxidative stress by removing and eliminating hydrogen peroxide free radicals.

SNP Active: A combination of Lactobacillus, Lactin, Phospholipids, Glycine, Olive Oil, and Vitamin E, which is known to help reduce skin aging.

TNF-α: Reduces inflammation.

SNP Active: A combination of Lactobacillus, Lactin, Phospholipids, Glycine, Olive Oil, and Vitamin E, which is known to help reduce skin aging.

EPH2: Maintains your skin's ability to absorb and penetrate active ingredients from external products.

SNP Active: A combination of Lactobacillus, Lactin, Phospholipids, Glycine, Olive Oil, and Vitamin E, which is known to help reduce skin aging.

MMP1: Regulates growth, collagen, elastin, and skin aging.

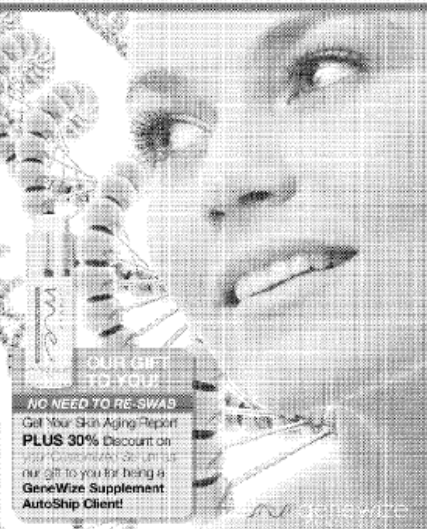
SNP Active: A combination of Lactobacillus, Lactin, Phospholipids, Glycine, Olive Oil, and Vitamin E, which is known to help reduce skin aging.

NOTES: GeneWise is not a medical product. It is a cosmetic product. It is not intended to treat or cure any disease. It is not intended to replace any medical treatment. It is not intended to be used as a substitute for medical advice. It is not intended to be used as a substitute for medical treatment.

LifeMap™ DNA Skin Repair Serum

Historic Evolution in Skin Care

Genetically Customized Skin Care Made Exclusively for You.



OUR GIFT TO YOU

NO NEED TO RE-SWAP

Get Your Skin Aging Report **PLUS 30% Discount** on your next purchase. Get your gift to you for being a GeneWise Supplement AutoShip Client!

To place an order go to www.geneWISE.com and log in to your account. Or call Customer Service at 888-355-8005.

Exhibit I

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Complaint

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Exhibit I

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Complaint

Exhibit J

GeneWise Life Sciences, Inc. ("GENEWIZE") Privacy Protection Policy:

GeneWise Life Sciences respects the privacy of every individual and has taken every precaution to create a process that allows individuals to maintain the highest level of privacy. All information provided by the individual taking the measures is kept on a secure server and all samples are identified by barcode only. This information is never shared with a third party. After the evaluation is completed and validated, all DNA sample material is destroyed. We will NEVER share any of your personal information with anyone.

- All SNP collection kits, swab and mailing envelopes are bar-coded for tracking and confidentiality.
- After receiving the swabs, the lab confirms and uploads the bar-coded samples for confidentiality, tracking, and control.
- The DNA is extracted from the swab and the lab amplifies the region of the DNA containing the SNP. The technique used to amplify the individual's DNA is called a polymerase chain reaction (PCR).
- The SNP is then detected with a proprietary technology, and a variety of important quality control systems are in place to ensure accuracy and repeatability.
- The results of the detected SNPs are then analyzed and compiled by special software and translated electronically into a confidential report called a LifeMap Healthy Aging Assessment™.

1. When you use our site, we receive and collect certain information. The information that we receive and collect depends on what you do when you visit GENEWISE.

Automatically Collected Information: Some information is automatically received and sometimes collected from you when you visit the GENEWISE site. We receive and collect the name of the domain and host from which you access the Internet; the Internet protocol (IP) address of the computer you are using; the browser software you use and your operating system; the date and time you access the site; and the Internet address of the web site from which you linked directly to our site. We use this information to monitor the usage of our site. Also, when we send emails to you, we may be able to identify information about your email address, such as whether you can read graphic-rich HTML emails. All of the information we automatically capture provides us with the ability to enhance our consumers' search and shopping experiences and to determine aggregate information about our user base and usage patterns.

Information Collected via Cookies: We use cookies to enhance the browsing and shopping experience on the GENEWISE site. "Cookies" are small files or records that we place on your computer's hard drive to collect information about your activities on GENEWISE site. The cookies transmit this information back to the computers at GENEWISE or our third-party

Exhibit J

Complaint

distributors of banners and newsletters; these computers are, generally speaking, the only computers which are authorized to read such information. The information captured makes it possible for us (i) to speed navigation, keep track of items in your shopping cart, and provide you with custom tailored content; (ii) to remember information you gave to us so you don't have to reenter it each time you visit the GENEWIZE site; (iii) to monitor the effectiveness of certain of our marketing campaigns; and (iv) to monitor total number of visitors, pages viewed, and the total number of banners served.

Most people do not know that cookies are being placed on their computers when they visit the GENEWIZE site or most web sites because browsers are typically set to accept cookies. You can choose to have your browser warn you every time a cookie is being sent to you or you can turn off cookie placement. If you refuse cookies, you will not be able to open a GENEWIZE Shopping Cart and therefore will not be able to complete an order with us online. Also, by not using cookies, your overall Internet browsing experience will be affected.

If you would like to obtain more information about the third-party distribution of banners on the GENEWIZE site and to know your choices about having such cookies turned off, please visit www.privacychoices.org. If you turn off the cookies, you will still see banners on our site; however, the banners will not be tailored to your shopping experience.

Information Collected Using Pixel Tags or Clear GIFs. To help us understand the effectiveness of certain of our email marketing efforts, GENEWIZE may use "message format" and "message open" sensing technologies. Both technologies require the use of pixel tags or clear GIFs (also called web beacons). The "message format" sensing technology allows us to recognize whether you have enabled your email program to receive HTML emails. If so, this information is then associated with your email address so that subsequent messages can be sent to you in HTML format. The "message open" sensing technology allows us to recognize whether you have opened our email message. We can only detect this if you have enabled your email program to receive HTML emails.

Information You Actively Submit to GENEWIZE. For most of the browsing services we provide, we neither require nor collect "Personal Customer Information" -- for example, email address, billing address, shipping address(es), phone number and credit card information. You can browse the GENEWIZE site and take as much time as you want to view our products and services without having to submit such Personal Customer Information. Even when you use our shopping cart as you browse, there is no need to submit Personal Customer Information.

In the following instance, however, we do need you to actively submit Personal Customer Information: when you want to become an Independent Business Owner (IBO), open an account or complete an order.

2. How we use and share Personal Customer Information

Occasionally, GENEWIZE uses Personal Customer Information to market products and services. GENEWIZE shares Personal Customer Information that we collect as follows:

Subcontractors. We send Personal Customer Information to third-party subcontractors and agents that work on our behalf to provide certain services. These third parties do not have the right to use the Personal Customer Information beyond what is necessary to assist us or fulfill your order. They are contractually obligated to maintain the confidentiality and security of the Personal

Exhibit J

Complaint

Customer information and are restricted from using such information in any way not expressly authorized by GENEWIZE.

Service Providers. We send Personal Customer Information to third-party providers of goods and services that you may purchase from time to time on our site (e.g., ISPs). Like subcontractors, these third parties do not have the right to use the Personal Customer Information beyond what is necessary to assist us. They are contractually obligated to maintain the confidentiality and security of the Personal Customer Information and are restricted from using such information in any way not expressly authorized by GENEWIZE.

Membership programs. We may work with certain companies who, in conjunction with their own membership programs or rewards programs, require that we disclose purchasing information about their customers who visit the GENEWIZE site through links from the partner sites, or use the partner's credit card to make purchases on the GENEWIZE site (e.g., to earn commissions for purchases made on the GENEWIZE site through outside links from the partner site, such as shared pay cards). We disclose only the information required to make these programs work and support your membership with them, which typically includes the name and/or email address of the user as well as the dollar amount of purchases made. We disclose this information to companies under an agreement that requires that they obtain your consent first, usually under the membership or participation rules. If you do not want us to disclose that information to the strategic partner, then you must contact them directly.

Credit card companies. Credit card transactions are handled by a third-party financial institution and their vendors, which receive the credit card number and other personal identifying information only to verify the card, card numbers and process transactions.

Law Enforcement Investigations. GENEWIZE may release Personal Customer Information when we believe, in our good judgment, that such release is reasonably necessary to comply with law, enforce or apply the terms of any of our policies or user agreements, or to protect the rights, property, or safety of GENEWIZE, our users, or others.

3. Communications from GENEWIZE

As a customer, you may receive the following communications from GENEWIZE: Communications related to transactions and account maintenance activities. These communications include without limitation: order confirmations, order update notices, order problem notices, and notices regarding material changes to site policies and account management procedures.

4. Underage customers

Our products and services are intended for purchase by adults or with the consent of adults. This is why GENEWIZE requires a credit card that has been authorized for use to complete purchases on our site.

5. Changes to Privacy Policy

This privacy policy was last changed on November 25, 2008. GENEWIZE reserves the right to modify or amend this policy at any time by posting the revised privacy policy on our site. The

Exhibit J

Complaint

changes will only affect the information we collect after the effective date of the change to our privacy policy unless we clearly express otherwise.

6. Questions or comments

If you have any questions regarding our privacy policy, please email at compliance@genewiz.com.

For all other inquiries, please contact customerservice@genewiz.com.

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Exhibit J

Decision and Order

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:

1. 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. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and this proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

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

- A. 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.
- B. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 44.
- C. “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.
- D. “Covered Assessment” means any genetic test or assessment, including, but not limited to, the Healthy Aging Assessment and LifeMap Healthy Aging Assessment.
- E. “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

Decision and Order

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.

- F. “Drug” means as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).
- G. “Food” means as defined in Section 15(b) of the FTC Act, 15 U.S.C. § 55(b).
- H. “Cosmetic” means as defined in Section 15(e) of the FTC Act, 15 U.S.C. § 55(e).
- I. “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.
- J. “Endorsement” means as defined in the Commission’s Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.0.
- K. “Licensee” means a person or entity, including a sublicensee, with whom respondent or its licensee has a business agreement.

Decision and Order

- L. “Affiliate” means any person or entity who participates in an Affiliate Program.
- M. “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.
- N. “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.
- O. The term “including” in this order means “without limitation.”
- P. 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.

Decision and Order

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

Decision and Order

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.

Decision and Order

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.

Decision and Order

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

Decision and Order

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

Decision and Order

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

Decision and Order

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

Decision and Order

(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, D.C. 20580. The subject line must begin: *In the Matter of GeneLink, Inc.*, FTC File No. 112 3095. *Provided, however*, that in lieu of

Decision and Order

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

Decision and Order

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

Decision and Order

Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 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 May 8, 2034, 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

Analysis to Aid Public Comment

later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen dissenting, and Commissioner McSweeney not participating.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

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, foruTM International Corporation, formerly known as GeneWize Life Sciences, Inc. (“foruTM”), sold through a multi-level marketing (“MLM”) network. According to the FTC complaint, GeneLink and foruTM 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

Analysis to Aid Public Comment

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;

Analysis to Aid Public Comment

- (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 foruTM 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

Analysis to Aid Public Comment

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*TM) 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

Analysis to Aid Public Comment

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.

Analysis to Aid Public Comment

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

Analysis to Aid Public Comment

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.

Concurring Statement

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.

**Statement of Chairwoman Edith Ramirez
and Commissioner Julie Brill**

We write to explain our support for the remedy imposed against respondents GeneLink, Inc. and Foru International Corporation, which we believe to be amply supported by the relevant facts. In this, as in all of the Commission's advertising actions alleging deceptive health claims, the Commission has called for, as proposed relief, a level of substantiation that is grounded in concrete scientific evidence and reasonably tailored to ensure that the conduct giving rise to the violation ceases and does not recur, among other important remedial goals. In our

Concurring Statement

view, the remedy adopted here accomplishes just that, without imposing undue costs on marketers or consumers more generally.

Respondents market and sell genetically customized nutritional supplements and topical skin products. As described in the complaint, this enforcement action stems from claims made by respondents in promotional materials and through testimonials that their products compensate for consumers' "genetic disadvantages" and cure or treat serious conditions such as diabetes, heart disease, and arthritis. In a newsletter, for example, respondents represented their products had cured "a serious diabetic and cardiac patient," and an affiliate's website stated that the products produced "improvements in everything from blood pressure to eczema to hormonal issues to arthritis."¹ The Commission alleges that respondents lacked adequate substantiation for these claims and that they falsely represented that the products' benefits were scientifically proven.

Disease treatment claims such as these require a rigorous level of substantiation. Based on evidence from genetics and nutritional genomics experts, the Commission has reason to believe that well-controlled human clinical trials (referred to here as "randomized controlled trials" or "RCTs") are needed to substantiate respondents' claims and that the studies relied on by respondents to back up their claims fall far short of this evidence. Because respondents lacked even one valid RCT for their products, it was unnecessary for the Commission to decide, for purposes of assessing liability, the precise number of RCTs needed to substantiate their claims.

In fashioning an appropriate remedy, however, we are requiring that respondents have at least two RCTs before making disease prevention, treatment, and diagnosis claims. We have the discretion to issue orders containing "fencing-in" provisions – "provisions . . . that are broader than the conduct that is declared unlawful." *Telebrands Corp. v. FTC*, 457 F.3d 354, 357 n.5 (4th Cir. 2006) (citation and internal quotation marks omitted). Here, we believe that the two-RCT mandate is appropriate and reasonably crafted to prevent the recurrence of

¹ Compl. Exs. G and H.

Concurring Statement

respondents' alleged unlawful conduct. This requirement conforms to well-recognized scientific principles favoring replication of study results to establish a causal relationship between exposure to a substance and a health outcome. *See, e.g., Thompson Med. Co.*, 104 F.T.C. 648, 720-21, 825 (1984) (requiring two RCTs to support claims of arthritis pain relief and thereby affirming determination that “[r]eplication is necessary because there is a potential for systematic bias and random error in any clinical trial”), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986).² It also provides clear rules for respondents, facilitating the setting of future research and marketing agendas, and preserves law enforcement resources by minimizing future argument over the quantity and quality of substantiation needed for the most serious health claims about respondents' products. Moreover, the deceptive claims alleged in the complaint are the type of significant violations of law for which fencing-in relief is more than justified as an additional safeguard against potential recidivism. *See, e.g., id.* at 834 (ruling that deceptive health claims about topical analgesic for arthritis pain warranted fencing-in, and noting that the seriousness of the violations was “affected by the fact that consumers could not readily judge the truth or falsity of the claims”).

While not taking issue with respondents' liability as alleged in the Commission's complaint, Commissioner Ohlhausen objects to the Commission's decision to require, as a remedial matter, that respondents have at least two RCTs before representing that their genetic products can cure, treat, diagnose, or prevent a disease. In addition to arguing that the two-RCT requirement is “unduly high,” Commissioner Ohlhausen expresses concern that these and other recent Commission orders may lead advertisers in general to believe that they too must invariably have two RCTs to substantiate health and disease claims for a variety of products, leading them to forgo otherwise

² *See also* GEOFFREY MARCZYK ET AL., ESSENTIALS OF RESEARCH DESIGN AND METHODOLOGY 15-16 (2005) (“The importance of replication in research cannot be overstated. Replication serves several integral purposes, including establishing the reliability (*i.e.*, consistency) of the research study's findings and determining . . . whether the results of the original study are *generalizable* to other groups of research participants.”).

Concurring Statement

adequately substantiated claims and depriving consumers of potentially useful information.³ We respectfully disagree.

There is nothing in our action today that amounts to the imposition of a “de facto two-RCT standard on health- and disease-related claims.”⁴ In this and other recent enforcement actions, the Commission has consistently adhered to its longstanding view that the proper level of substantiation for establishing liability is a case-specific factual determination as to what constitutes competent and reliable scientific evidence for the advertising claims at issue.⁵ The same fact-specific approach has guided the Commission’s remedial standards. Recent Commission consent orders concerning different types of health claims have variously required two RCTs,⁶ one RCT,⁷ or more

³ Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part [hereinafter Ohlhausen Statement] at 1. In her Statement, Commissioner Ohlhausen also references various weight-loss related enforcement actions announced today by the Commission, including *FTC v. Sensa Products, LLC*. Her objections, however, center on the remedy imposed in this matter.

⁴ Ohlhausen Statement at 3.

⁵ See, e.g., *Bristol Meyers Co.*, 102 F.T.C. 21, 332-38 (1983), *aff’d*, 738 F.2d 554 (2d Cir. 1984); FTC, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 10 (Apr. 2001) [hereinafter DIETARY SUPPLEMENTS ADVERTISING GUIDE] (“When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate.”).

⁶ See, e.g., *FTC v. Skechers U.S.A., Inc.*, No. 1:12-cv-01214-JG (N.D. Ohio July 12, 2012) (prohibiting, as a remedial matter, weight loss claims without two RCTs); *FTC v. Labra*, No. 11 C 2485 (N.D. Ill. Jan. 11, 2012) (same); *FTC v. Iovate Health Scis.USA, Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (same); *Nestlé Healthcare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (requiring two RCTs for claims that any probiotic drink or certain nutritionally complete drinks reduce the duration of acute diarrhea in children or absences from daycare or school due to illness).

⁷ See, e.g., *FTC v. Skechers U.S.A., Inc.*, No. 1:12-cv-01214-JG (N.D. Ohio July 12, 2012) (prohibiting muscle strengthening claims for any footwear product without one RCT); *FTC v. Reebok Int’l Ltd.*, No. 1:11-cv-02046-DCN (N.D. Ohio Sept. 29, 2011) (same).

Concurring Statement

generally defined “competent and reliable scientific evidence.”⁸ Against this backdrop, we are not persuaded that by requiring two RCTs as a remedial matter here, the Commission will create a misperception among advertisers about the substantiation standards that govern liability for deceptive advertising.⁹ However, to the extent other marketers look to our orders for signals as to the type of backing required for disease treatment claims, we prefer that they understand that serious claims like those made by respondents must have hard science behind them.

We also disagree that the proposed remedy will deny consumers access to useful information about new areas of science. The value of information naturally depends on its accuracy.¹⁰ As the D.C. Circuit has emphasized, “misleading advertising does not serve, and, in fact, disservices, th[e] interest”

⁸ See, e.g., *NBTY, Inc.*, 151 F.T.C. 201 (2011) (requiring marketer of vitamins to possess “competent and reliable scientific evidence” for any claim about the health benefits, performance, or efficacy of any product).

⁹ Moreover, as Commissioner Ohlhausen notes, Ohlhausen Statement at 2 n.7, there may be some instances in which the medical community would not require RCTs to demonstrate that a substance treats, prevents, or reduces the risk of a disease. See, e.g., *DIETARY SUPPLEMENTS ADVERTISING GUIDE*, *supra* note 5, at 11 (explaining that an appropriately qualified claim based on epidemiological evidence would be permitted where “[a] clinical intervention trial would be very difficult and costly to conduct,” “experts in the field generally consider epidemiological evidence to be adequate” and there is no “stronger body of contrary evidence”). But, contrary to Commissioner Ohlhausen’s contention, the link between folic acid and neural tube birth defects was substantiated using a combination of RCTs and observational epidemiological evidence, as indicated by the articles she cites. See, e.g., Walter C. Willett, *Folic Acid and Neural Tube Defect: Can’t We Come to Closure?*, 82 AM. J. PUB. HEALTH 666, 667 (1992).

¹⁰ In some instances, “emerging” scientific evidence has been subsequently contradicted by further research, leading to consumer confusion and potential physical and financial harm. See, e.g., Eric A. Klein et al., *Vitamin E and the Risk of Prostate Cancer, The Selenium and Vitamin E Cancer Prevention Trial (SELECT)*, 306 J. AM. MED. ASS’N 1549, 1551 (2011) (reporting that a 2008 randomized, placebo-controlled prospective clinical trial of over 35,000 men contradicted “considerable preclinical and epidemiological evidence that selenium and vitamin E may reduce prostate cancer risk,” and that follow-up observational data from 2011 showed a statistically significant increase in prostate cancer in the vitamin E group over placebo).

Concurring Statement

of “consumers and society . . . in the free flow of commercial information.” *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43 (D.C. Cir. 1985) (citation and internal quotation marks omitted). If respondents wish to rely on emerging science, they can qualify their claims accordingly. Properly qualified claims are lawful and permissible under our proposed orders. *See Proposed Consent Orders, Part III.*

The fact that the ingredients in respondents’ products are safe also does not alter our conclusion. Consumers who rely on respondents’ claims may forgo important diet and lifestyle changes that are known to reduce the risk of diabetes, heart disease, or arthritis. Or they may forgo treatments that, unlike respondents’ products, have been demonstrated to be effective. In addition, respondents charge a premium, over \$100 per month, for their customized products. Consumers, therefore, may be deceived both to their medical and economic detriment when a safe product provides an ineffective treatment. *See FTC v. QT, Inc.*, 512 F.3d 858, 863 (7th Cir. 2008) (safe but deceptively advertised treatment “will lead some consumers to avoid treatments that cost less and do more; the lies will lead others to pay too much for [treatment] or otherwise interfere with the matching of remedies to medical conditions”); *Pfizer Inc.*, 81 F.T.C. 23, 62 (1972) (“A consumer should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented.”). Unsubstantiated disease claims also harm honest competitors that expend considerable resources on studies or analyses of the existing science and conform their advertising claims accordingly. Allowing companies to rely on “emerging” evidence to support disease claims merely because the products in question are safe would risk a “race to the bottom” – the proliferation of progressively more egregious disease claims, which would harm both legitimate competitors and consumers in the process.

Finally, Commissioner Ohlhausen argues that requiring the RCTs to be conducted by different researchers working independently of each other imposes undue burdens in the absence of evidence that a defendant has fabricated or interfered

Concurring and Dissenting Statement

with a study or its results.¹ This requirement is an important safeguard that lessens the likelihood that researcher bias will affect the outcome of a study and helps ensure that the results are replicable.²

In short, we believe the relief obtained by the Commission in this settlement is warranted and strikes the right balance between the need for accuracy in health-related advertising claims and the burden placed on respondents.

**STATEMENT OF COMMISSIONER MAUREEN K. OHLHAUSEN
DISSENTING IN PART AND CONCURRING IN PART**

I strongly support the Commission's enforcement efforts against false and misleading advertisements and therefore have voted in favor of the consent agreements with Sensa Products, LLC; HCG Diet Direct, LLC; L'Occitane, Inc.; and LeanSpa, LLC, despite having some concerns about the scope of the relief in several of these weight-loss related matters. I voted against the consent agreements in the matter of GeneLink, Inc. and foru International Corporation, however, because they impose an unduly high standard of at least two randomized controlled trials

¹ Ohlhausen Statement at 2-3.

² Commissioner Ohlhausen also objects to the Part I requirement that testing be conducted on the product about which the advertising claim is made or an "essentially equivalent product," arguing that the order should authorize "claims regarding individual ingredients in combined products as long as claims for each ingredient are properly substantiated and there are no known interactions." Ohlhausen Statement at 3. In fact, the orders permit that very thing. If there is reliable evidence that the additional ingredients will not interact with the tested product in a way that impacts efficacy, the orders do not require testing of the combined product. See Proposed Consent Orders at 3 (defining "Essentially Equivalent Product" to permit additional ingredients, beyond those in the tested product, if "reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients [in the respondent's product] is unlikely to impede or inhibit the effectiveness of the ingredients in the [tested product]").

Concurring and Dissenting Statement

(or RCTs) to substantiate *any* disease-related claims, not just weight-loss claims. Adopting a one-size-fits-all approach to substantiation by imposing such rigorous and possibly costly requirements for such a broad category of health- and disease-related claims³ may, in many instances, prevent useful information from reaching consumers in the marketplace and ultimately make consumers worse off.⁴

The Commission has traditionally applied the *Pfizer*⁵ factors to determine the appropriate level of substantiation required for a specific advertising claim. These factors examine the nature of the claim and the type of product it covers, the consequences of a false claim, the benefits of a truthful claim, the cost of developing the required substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable for such a claim.⁶ One of the goals of the *Pfizer* analysis is to balance the value of greater certainty of information about a product's claimed attributes with the risks of both the product itself and the suppression of potentially useful information about it. Under such an analysis, the burden for substantiation for health- or disease-related claims about a safe product, such as a food, for example, should be lower than the burdens imposed on

³ This provision may apply quite broadly in practice given the Commission majority's conclusion in our *POM Wonderful* decision that many of the claims involving the continued healthy functioning of the body also conveyed implied disease-related claims. See *POM Wonderful, LLC*, No. 9344, 2013 WL 268926 (F.T.C. Jan. 16, 2013).

⁴ To be clear, however, I am not advocating in favor of permitting "unsubstantiated disease claims," as suggested in the statement of Chairwoman Ramirez and Commissioner Brill. Rather, I am suggesting that consumers would on balance be better off if we clarified that our requirements permit a variety of health- or disease-related claims about safe products, such as foods or vitamins, to be substantiated by competent and reliable scientific evidence that might not comprise two RCTs.

⁵ *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

⁶ *Id.* at 91-93; see also *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984)).

Concurring and Dissenting Statement

drugs and biologics because consumers face lower risks when consuming the safe product.⁷

Recently, however, Commission orders, including the ones in the matter of GeneLink and foru International, seem to have adopted two RCTs as a standard requirement for health- and disease-related claims for a wide array of products.⁸ RCTs can be difficult to conduct and are often costly and time-consuming relative to other types of testing, particularly for diseases that develop over a long period of time or complex health conditions. Requiring RCTs may be appropriate in some circumstances, such as where use of a product carries some significant risk, or where the costs of conducting RCTs may be relatively low, such as for conditions whose development or amelioration can be observed over a short time period. Thus, I am willing to support the order requirement of two RCTs for short-term weight loss claims in the Sensa, HCG Diet Direct, L'Occitane, and LeanSpa matters because such studies can be conducted in a relatively short amount of time at a lower cost than for many other health claims. My concern with GeneLink and foru International and the series of similar orders is that they might be read to imply that two RCTs are required to substantiate any health- or disease-related claims, even for relatively-safe products. It seems likely that producers may forgo making such claims about these kinds of

⁷ The FDA designates most food ingredients as GRAS (generally recognized as safe). 21 C.F.R. § 170.30. Vitamins and minerals are treated as foods by the FDA and are also GRAS. See FDA Guidance for Industry: Frequently Asked Questions about GRAS (Dec. 2004), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm#Q1>. As a result, food ingredients, vitamins, and minerals can be combined and sold to the public without direct evidence on the particular combination realized in the new product. Many products are made up of several common generic ingredients, for which there is little financial incentive to test individually or to retest in each particular combination.

⁸ The orders in this matter include as a Covered Product any food, drug, or cosmetic that is genetically customized or personalized for a consumer or that is promoted to modulate the effect of genes. Other cases requiring two RCTs are *POM Wonderful LLC*, Docket No. 9344 (F.T.C. Jan. 10, 2013) (fruit juice); *Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (yogurt); *Nestlé Healthcare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (food); *FTC v. Iovate Health Sci. USA, Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (dietary supplement).

Concurring and Dissenting Statement

products, even if they may otherwise be adequately supported by evidence that does not comprise two RCTs.⁹

Although raising the requirement for both the number and the rigor of studies required for substantiation for all health- or disease-related claims may increase confidence in those claims, the correspondingly increased burdens in time and money in conducting such studies may suppress information that would, on balance, benefit consumers. If we demand too high a level of substantiation in pursuit of certainty, we risk losing the benefits to consumers of having access to information about emerging areas of science and the corresponding pressure on firms to compete on the health features of their products. In my view, the Commission should apply the *Pfizer* balancing test in a more finely calibrated manner than they have in the GeneLink and *Foru International* orders to avoid imposing “unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions.”¹⁰

In addition, based on the same concerns about imposing unnecessarily burdensome and costly obligations, I do not support a general requirement that all products be tested by different researchers working independently without an indication that the defendant fabricated or otherwise interfered with a study or its results.¹¹ Where defendants have fabricated

⁹ Notably, the medical community does not always require RCTs to demonstrate the beneficial effects of medical and other health-related innovations. For example, the recommendation that women of childbearing age take a folic acid supplement to reduce the risk of neural tube birth defects was made without RCT evidence on the relevant population. See Walter C. Willett, “Folic Acid and Neural Tube Defect: Can’t We Come to Closure?” *American Journal of Public Health*, May 1992, Vol. 82, No. 5; Krista S. Crider, Lynn B. Bailey and Robert J. Berry, “Folic Acid Food Fortification—Its History, Effect, Concerns, and Future Directions,” *Nutrients* 2011, Vol. 3, 370-384.

¹⁰ FTC Staff Comment Before the Food and Drug Administration In the Matter of Assessing Consumer Perceptions of Health Claims, Docket No. 2005N-0413 (2006), available at <http://www.ftc.gov/be/V060005.pdf>.

¹¹ The FDA does not require independent testing for clinical investigational studies of medical products, including human drug and biological products or medical devices, and it permits sponsors to use a variety of approaches to fulfill

Concurring and Dissenting Statement

results, as our complaint against Sensa alleges, a requirement of independent testing may be appropriate, but a simple failure to have adequate substantiation should not automatically trigger such an obligation. In other cases, where there is some concern about a sponsor or researcher biasing a study, our orders may address this in a less burdensome way by requiring the producer making the disease-related claims to provide the underlying testing data to substantiate its claims, which we can examine for reliability. Similarly, the requirement to test an “essentially equivalent product,” which appears to be more rigorous than FDA requirements for food and supplement products, can significantly and unnecessarily increase the costs of substantiation, again potentially depriving consumers of useful information. Instead, Commission orders should clearly allow claims regarding individual ingredients in combined products as long as claims for each ingredient are properly substantiated and there are no known relevant interactions.¹²

It is my hope and recommendation that as we consider future cases involving health- and disease-related claims, the Commission and its staff engage in a further dialogue about our substantiation requirements to discern how best to assess the potential costs and benefits of allowing different types of evidence that might provide a reasonable basis to substantiate such claims. Although I am willing to support liability for

their responsibilities for monitoring. See FDA Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring (Aug. 2013), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf>.

¹² Although the statement by Chairwoman Ramirez and Commissioner Brill asserts that the orders in *GeneLink* and *foru International* permit claims for individual ingredients in combined products as long as the claims for each ingredient are properly substantiated and there are no known interactions, the orders actually require that “reliable scientific evidence generally accepted by experts in the field demonstrate that the amount and *combination of additional ingredients* is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.” Decision and Order at 2, *In the Matter of GeneLink, Inc.* FTC File No. 112 3095 (emphasis added). My point is that the FDA does not require direct evidence regarding *combinations of individual ingredients deemed GRAS* but the order on its face requires scientific evidence demonstrating the effect of such combinations.

Concurring Statement

failures to have adequate substantiation for health- and disease-related claims under certain circumstances, I am not willing to support a de facto two-RCT standard on health- and disease-related claims for food or other relatively-safe products.

Statement of Commissioner Joshua D. Wright

Today the Commission announces five settlements involving the deceptive marketing of a variety of nutritional and dietary supplements, skincare products, and weight-loss remedies. While the course of business conduct, type of product and particular advertising claim at issue in each case differs, all share one common characteristic – the Commission has alleged that, in the course of advertising their products, each of these defendants has made false or unsubstantiated claims about the treatment of certain medical or health conditions.

Cases that challenge false or unsubstantiated claims – especially those involving serious medical conditions – are an important component of our agency’s mission to protect consumers from economic injury. Indeed, the aggregate consumer injury in these particular matters is estimated to be \$420 million and these settlement agreements will return approximately \$33 million to consumers. I fully support the Commission’s efforts to deter deceptive advertising and voted in favor of authorizing these particular settlements.

In crafting remedial relief in these cases, the Commission inevitably faces a tradeoff between deterring deceptive advertising and preserving the benefits to competition and consumers from truthful claims. Tailoring remedial relief – including the level of substantiation required – to the specific claims at issue is in the best interests of consumers.¹ I write today to express some of my views on this issue.

¹ The Commission’s determination of whether an advertiser has adequate substantiation in the first instance depends upon “a number of factors relevant

Concurring Statement

Each of the consent agreements announced today includes injunctive relief provisions requiring the settling parties to satisfy a standard of “competent and reliable scientific evidence” before again making the claims at issue. Each consent agreement further defines “competent and reliable scientific evidence” as requiring, among other things, two adequate and well-controlled human clinical studies (randomized controlled trials or RCTs) of the product. I encourage the Commission to explore more fully whether the articulation and scope of injunctive relief in these and similar settlements strikes the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims. The optimal amount and type of evidence to substantiate a future claim will vary from case to case. Similarly, a fact-specific inquiry may justify specially crafted injunctive relief in certain cases, such as bans, performance bonds or document retention requirements for underlying study data. I look forward to working with my fellow Commissioners to continue to examine and evaluate our formulation of the competent and reliable scientific evidence standard, as well as the ancillary injunctive provisions in consent agreements, in order to best protect consumers from the costs imposed upon them by deceptive advertising while encouraging competition and truthful advertising that benefits consumers.

to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.” FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Formulating the required level of substantiation for injunctive relief should necessarily be grounded in the factors set forth in this policy statement, although additional considerations might also be relevant.

Complaint

IN THE MATTER OF

FORU™ INTERNATIONAL CORPORATION
F/K/A
GENEWIZE LIFE SCIENCES, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4457; File No. 112 3095
Complaint, May 8, 2014 – Decision, May 8, 2014

This consent order addresses foru™ International Corporation f/k/a GeneWize Life Sciences, Inc.'s advertising and promotion of purported genetically customized nutritional supplements and skin repair serum products, which foru™ sold through a multi-level marketing network. The complaint alleges that 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 further alleges 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. Additionally, the complaint alleges that foru™ failed to provide reasonable and appropriate security for consumers' personal information. The consent order requires foru™ 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 order also prohibits foru™ 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 respondent relies 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.

Participants

For the Commission: Megan Cox, Keith Fentonmiller, Carolyn L. Hann, Mary L. Johnson, and Laura Riposo VanDruff.

For the Respondent: Holly Bayne, The Law Office of Bayne & Associates; and David V. Kirby, O'Connor & Kirby.