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FEDERAL TRADE COMMISSION

[File No. 192 3170]

Vitagene, Inc.; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write "Vitagene, Inc.; File No. 192 3170" on your comment and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex V), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: James Trilling (202-326-3497), or Elisa Jillson (202-326-3001), Attorneys, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Ave. NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule § 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of 30 days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions*.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write "Vitagene, Inc.; File No. 192 3170" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. If you prefer to file your comment on paper, write "Vitagene, Inc.; File No. 192 3170" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex V), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov*, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification

number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule § 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at *http://www.ftc.gov* to read this document and the news release describing the proposed settlement. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's

privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy*.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission (the "Commission") has accepted, subject to final approval, an agreement containing a consent order from 1Health.io Inc. (formerly known as, and doing business as, Vitagene, Inc.) ("Vitagene"). The proposed consent order ("proposed order") has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission again will 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.

Since 2015, Vitagene has sold "DNA Health Test Kits" to consumers. In each DNA Health Test Kit, Vitagene instructs the consumer to provide a saliva sample by mail. Vitagene contracts with a testing lab to analyze the sample and map a portion of the consumer's genetic code.

Vitagene combines the testing lab's DNA analysis with the consumer's answers to an online "health questionnaire" that probes the individual's health history, lifestyle, and family health history. Using this information, Vitagene generates reports about the consumer's health and wellness ("Health Reports") and ancestry. Vitagene also sells to the consumer Health Reports that it creates by using the consumer's answers to an online "lifestyle questionnaire" and raw DNA data that the consumer sends to Vitagene after the consumer has obtained DNA tests from certain companies other than Vitagene. The retail cost for a package that includes a Health Report has ranged from $29 to $259, with higher-priced packages including add-ons such as subscriptions to personalized vitamin packs and nutritional coaching.

The Health Reports that Vitagene creates contain numerous facts about the consumer's genetics and health. For example, one type of Health Report first lists the consumer's name, date of birth, and referring doctor or dietician, and then identifies salient genotype data, pertinent questionnaire answers, and, based on the genotype data and questionnaire answers, the level of risk for having or developing certain health conditions, such as high LDL cholesterol, high triglycerides, obesity, or blood clots.

As part of its information technology infrastructure, Vitagene stores consumers' health and genetic information in the Amazon Web Services ("AWS") Simple Storage Service (the "Amazon S3 Datastore") in virtual containers, called "buckets." The files Vitagene has stored in Amazon S3 Datastore buckets include, among other things, consumers' Health Reports; genotype data called single-nucleotide polymorphisms ("SNPs"), which are the most common type of genetic variation among people; and other raw genotype data.

The proposed complaint alleges that, despite the fact that Vitagene has stored consumers' sensitive personal information in the Amazon S3 Datastore, Vitagene did not uniformly apply basic safeguards to the data in each of its Amazon S3 Datastore buckets. In particular, the proposed complaint alleges that, in or about 2016, Vitagene created a publicly accessible bucket in which the company stored Health Reports for at least 2,383 consumers and a publicly accessible bucket in which it stored raw genetic data (sometimes accompanied by first name) for at least 227 consumers. The proposed complaint alleges that Vitagene's failure to use access controls to restrict access to this sensitive data, encrypt it, log or monitor access to it, or inventory it, to help ensure ongoing security resulted in Vitagene publicly exposing the data until July 2019. According to the proposed complaint, between July 2017 and June 2019, Vitagene received at least three warnings that it was storing consumers' unencrypted health, genetic, and other personal information in publicly accessible buckets.

The proposed complaint alleges Vitagene changed its name from Vitagene, Inc. to 1Health.io Inc. in October 2020. According to the proposed complaint, the company published revised privacy policies in April and December 2020 that apply to all hthe company's customers, including those who purchased products and services from the company solely before April 2020. The proposed complaint alleges that, compared to Vitagene's previous privacy policy, the company's 2020 privacy policies significantly expand the types of third parties with whom, and the purposes for which, the company may share consumers' sensitive personal information. The company did not provide direct notice to consumers of the change, but it also did not implement the expanded sharing.

The proposed five-count complaint alleges that Vitagene violated section 5(a) of the FTC Act by misrepresenting the company's data security and privacy practices, and by unfairly making material retroactive changes to the company's policies regarding third-party sharing of sensitive personal information.

Proposed complaint Count I alleges Vitagene deceived consumers by misrepresenting that it exceeded industry-standard security practices. On a webpage that Vitagene devoted to describing its privacy practices, Vitagene claimed that "[w]e use the latest technology and exceed industry-standard security practices to protect your privacy." The proposed complaint alleges that Vitagene's public exposure of consumers' Health Reports, raw genetic data, and other personal information in AWS S3 buckets until July 2019 contradicted this claim.

Proposed complaint Count II alleges Vitagene deceptively claimed on multiple webpages that it stored consumers' DNA results without name or any other common identifying information. The proposed complaint alleges that this claim was deceptive because Vitagene stored consumers' DNA results with their names and other common identifying information.

Proposed complaint Count III alleges Vitagene deceptively claimed that it would remove all of a consumer's information if the consumer requested deletion of his or her data. Vitagene made this claim on a webpage that Vitagene devoted to describing its privacy practices. The proposed complaint alleges that the claim was deceptive because, from approximately 2016 through July 1, 2019, Vitagene's lack of a data inventory made it impossible for the company to search comprehensively in response to consumers' requests for Vitagene to delete their data.

Proposed complaint Count IV alleges Vitagene deceived consumers by claiming on multiple webpages that it destroys consumers' physical DNA saliva samples shortly after analysis of them. The proposed complaint alleges that this claim was deceptive because, beginning in approximately December 2016, Vitagene did not have a contract provision with its genotyping laboratory partner requiring such destruction.

Proposed complaint Count V alleges it was unfair for Vitagene to post on its websites in April and December 2020 revised privacy policies that describe materially expanded practices for the company's sharing of consumers' sensitive health and genetic information with third parties—including the information of consumers who purchased products and services from Vitagene solely before April 2020—without taking any additional steps to notify consumers or obtain consumers' consent.

The proposed order contains provisions to address Vitagene's conduct and prevent it from engaging in the same or similar acts or practices in the future. Part I of the proposed order prohibits Vitagene from misrepresenting (1) the extent to which it meets or exceeds industry-standard security or privacy practices, (2) the extent to which it stores any Health Information (as defined in the order) with any other element of Personal Information (as also defined in the order), (3) the extent to which, or the purposes for which, it collects, uses, discloses, maintains, deletes, or destroys a consumer's (i) physical DNA sample or (ii) Personal Information upon request, (4) it is a member of, adheres to,

complies with, is certified by, or otherwise participates in, any privacy or security program sponsored by a government entity or third party, (5) the extent to which it otherwise protects the privacy, security, availability, confidentiality, or integrity of Personal Information, or (6) it has received approval or authorization for its claims, products, or services from any government agency.

Part II prohibits Vitagene from disclosing Health Information to any Third Party (as defined in the order) unless the company obtains the Affirmative Express Consent (as also defined in the order) of the individual who is identifiable by the Health Information. Part III requires Vitagene to instruct any laboratory that collected physical DNA samples pursuant to a contract with Vitagene to destroy any such sample that the laboratory retained for more than 180 days after Vitagene accepted the results of the analysis of the sample.

Part IV requires Vitagene to establish, implement, and maintain a comprehensive information security program that protects the security, confidentiality, and integrity of Personal Information. Part V requires Vitagene to obtain initial and biennial data security assessments from a third-party assessor for twenty years. Part VI requires Vitagene to disclose all material facts to the assessor and prohibits Vitagene from misrepresenting any fact material to the assessments required by Part V.

Part VII requires Vitagene to submit to the Commission an annual certification that Vitagene has implemented the requirements of the Order and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission. Part VIII requires Vitagene to submit a report to the Commission if it discovers any Covered Incident (as defined in the order).

Part IX requires Vitagene to pay $75,000 in monetary relief. Part X provides that the Commission may use Vitagene's monetary relief payment to provide, and pay expenses related to the administration of, consumer redress. Part XI requires Vitagene to

provide the Commission customer information to enable the Commission to efficiently administer consumer redress.

Parts XII-XV are reporting and compliance provisions. Part XII requires Vitagene to acknowledge receipt of the order and distribute it to persons with responsibilities relating to the subject matter of the order. Part XIII requires Vitagene to submit an initial compliance report to the Commission and notify the Commission of changes in Vitagene's corporate status. Part XIV requires Vitagene to create and retain certain documents relating to its compliance with the order. Part XV requires that Vitagene provide the Commission additional information or compliance reports, as requested. Part XVI states that the proposed order will remain in effect for 20 years, with certain exceptions.

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

By direction of the Commission.

April J. Tabor,

Secretary.

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