STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 20, 2016

Steven Cahillane, CEO
NBTY, Inc..
2100 Smithtown Ave
Ronkonkoma, NY 11779

Dear Mr. Cahillane:

This letter memorializes an agreement between the New York State Office of the Attorney General ("NYAG") and NBTY, Inc. ("NBTY").

Background

In early 2015, NYAG commenced an investigation into the authenticity, purity, and related marketing claims associated with certain herbal supplements sold by four major retailers in New York, including Walgreens and Walmart. NYAG commissioned a study (the "NYAG Study") that utilized DNA barcoding[1] to test specific lots of six herbal supplements, including Echinacea, Garlic, Gingko Biloba, Ginseng, Saw Palmetto, St. John's Wort, or associated extracts (the "Tested Supplements"). The Tested Supplements included specific lots of herbal supplements NBTY manufactured for Walgreens and Walmart (the "NBTY Supplements").

In letters dated February 2, 2015, NYAG informed Walmart, Walgreens, and the other retailers that the NYAG Study did not detect identifiable genetic material for the plants depicted on the relevant labels for most of the Tested Supplements, but detected DNA associated with other plants, including potential allergens, contaminants, or unlabeled fillers.

The letters expressed NYAG's concerns about the measures that manufacturers and retailers relied on to ensure the authenticity and purity of herbal supplements. As NYAG had requested, the four retailers removed the Tested Supplements from their store shelves.

[1] DNA barcoding is a technique that uses short, signature sequences of DNA to identify the plant source.

The federal Food and Drug Administration ("FDA") does not mandate the use of DNA-based technologies, like DNA barcoding, to authenticate herbal supplements. Instead, the agency permits companies to support their claims through the use of one or more scientifically valid methodologies, including chemical profiling methods of the types employed by NBTY.

NYAG's position is that, given the existence of chemically-similar natural or synthetic substitutes, using existing chemical testing methodologies alone provides inadequate assurance of the identity and authenticity of herbal supplements. NYAG's position is also that, in many instances, existing testing measures fail to adequately detect the presence of known organic contaminants, including allergens, or unidentified fillers. NYAG believes that DNA barcoding provides a powerful and scientifically valid method for identifying potential fraud and contamination in the herbal supplement supply chain.

NBTY cooperated with NYAG's investigation, providing documentation of its manufacturing practice and testing regimes. NYAG found no evidence in the course of its investigation that NBTY deviated from, or failed to administer, the testing procedures mandated by the FDA's "Current Good Manufacturing Practices" ("cGMPs") rules or standard industry practice in the production of the NBTY manufactured herbal dietary supplements at issue in this investigation ("Tested Supplements"). NBTY also provided documentation (directly and through its retail customers) of the scientific testing protocols and quality control methods that NBTY employed on the Tested Supplements stating that the Tested Supplements met the standards of FDA cGMP requirements.

NBTY's position is that the DNA testing of herbal dietary supplements is an emerging science in its developmental stages, and at this time chemical and other testing methodologies and quality control and tracking processes exist that are properly validated and reliable for establishing the authenticity of herbal supplements. Specifically, NBTY's position is that scientifically verified standards and methodologies utilizing DNA testing that could be considered accurate and reliable do not exist for establishing the authenticity of finished herbal dietary supplements. NBTY's position is also that current DNA testing technology cannot accurately or reliably determine whether finished herbal dietary supplements include potential allergens, contaminants, or unlabeled fillers.

NBTY nevertheless has stated a shared commitment with NYAG to promote the development of the most accurate, reliable standards and testing methods to confirm the appropriate identity of herbal plant compounds contained within herbal dietary supplements. NBTY has therefore committed to improve transparency and assure authenticity and quality of Herbal Dietary Supplements,[2] including through a new Herbal Authenticity Program, and agrees to the terms of this agreement, among other things, to advance the development and implementation of DNA testing as an additional technology to benefit consumers.

[2] For purposes of this Agreement, "Herbal Dietary Supplements" means products that: (i) are manufactured by, or at the direction of, NBTY or any of its subsidiaries or agents; (ii) sold anywhere in the United States; *and* (iii) have a plant or plant part in the product name, whether referred to by the common name, the Latin binomial, another name, or a combination thereof.

NBTY Commitments

NBTY commits to:

1. **Develop and incorporate improved herbal authentication methodologies, including DNA barcoding.**

    a. *Establish Herbal Authenticity Program.* To support NYAG's efforts to improve herbal authentication processes, NBTY has initiated an Herbal Authenticity Program, which seeks, among other things, to further enhance the accuracy and reliability of standards and testing methods used to identify and authenticate Herbal Dietary Supplements sold in the United States, including DNA barcoding. NBTY will share the results of its Herbal Authenticity Program publicly and across the industry to promote the continued development and implementation of scientifically verified standards and methodologies.

    b. *DNA Testing of Herbal Supplements – Phase I.* As soon as practicable, but beginning no later than 12 months from the signing of this Agreement, and continuing thereafter, NBTY agrees to implement a DNA barcoding protocol, as either a standalone method or part of a multi-method protocol, to confirm the plant identity of herbal ingredients (regardless of form) derived from at least twelve (12) distinct herbal species used in Herbal Dietary Supplements prior to their use in any Herbal Dietary Supplements.

    c. *DNA Testing of Herbal Supplements – Phase II.* As soon as practicable, but beginning no later than 24 months from the signing of this Agreement, and continuing thereafter, NBTY agrees to implement a DNA barcoding protocol, as either a standalone method or part of multi-method protocol, to confirm the identity of all herbal ingredients prior to their use in any Herbal Dietary Supplements, where reliable and scientifically valid DNA barcoding is available for confirming the plant identity of the relevant herbal ingredient.[3]

    d. *Engagement of Raw Material Suppliers/Commercial Labs.* Through its Herbal Authenticity Program, NBTY will work with raw material suppliers to collaborate to develop additional reliable and scientifically validated testing methods to

[3] For purposes of this provision, reliable and scientifically valid DNA barcoding is presumed available for confirming the plant identity of the relevant herbal ingredient upon the happening of any one or more of the following events: (1) DNA barcoding is incorporated in a monograph associated with the relevant ingredient by the United States Pharmacopeia or the American Herbal Pharmacopeia; (2) the U.S. Food and Drug Administration accepts or endorses the use of DNA barcoding, either as a standalone method or part of a multi-method protocol, as a scientifically valid method for confirming the identity of the relevant ingredient; (3) any U.S. industry group in which NBTY is a corporate member identifies DNA barcoding as a valid or appropriate method for confirming the authenticity of the relevant ingredient, as either a standalone method or part of a multi-method protocol; or (4) upon review of scientific literature and industry practice, NBTY or its Herbal Authenticity Program independently recognizes that reliable and scientifically valid DNA barcoding is available for that ingredient.

determine the identity and authenticity of herbal dietary supplements, including DNA standards and testing for herbal materials.

e. *Engagement with Scientific Institutions.* Through its Herbal Authenticity Program, NBTY commits to partner with scientific institutions to further the development of uniform standards to authenticate herbs and contribute to the development of public genetic standards libraries. NBTY will invest $250,000 in herbal authenticity genetic research and education in the first year, and will continue its efforts over the next 24 months to establish conclusive partnerships to improve the authenticity of herbal ingredients.

Specifically, NBTY intends, and will take concrete steps, to partner with Cornell University and other scientific institutions (such as the National Center for Natural Products Research at the University of Mississippi) to further the transparency and traceability of herbal dietary supplements, including through DNA barcoding, where appropriate. The program will be managed by NBTY's Nutrition and Scientific Affairs Department under the direct supervision of the Chief Scientific Officer from its New York locations across a network of partners.

2. **Promote Good Manufacturing Practices.**

a. Beginning immediately and during the next 24 months, NBTY will actively support the establishment of Good Manufacturing Practices Guidelines for Botanical Raw Material through industry associations to further authenticate and track plant material from the harvesting of plants to testing of the raw material, and commits to adopt such Guidelines within that timeframe (to the extent not inconsistent with this agreement).

b. NBTY will require that all "active" botanical ingredients supplied by NBTY's herbal suppliers and used in Herbal Dietary Supplements will be manufactured in GMP compliant facilities and that their facilities be certified through a third-party accreditation body.

3. **Implement Supplier Site Risk Assessment.** NBTY will pursue improvements in quality procedures with its suppliers designed to ensure the authenticity of the herbs from harvest to consumption.

a. NBTY will increase its herbal audit presence to verify herbal identification and authenticity measures from 12 to 24 on-site assessments annually with major herbal suppliers. The audits will take place in the 12 months from October 2016 to October 2017 and will become an ongoing program to ensure proper herbal identification and authenticity testing for all lots received from major herbal suppliers to NBTY.

b. NBTY will require its major herbal suppliers to provide appropriate certification of supplier oversight (including periodic audits) at the manufacturing location

using applicable industry standards and internationally recognized herbal medicinal standards as the audit standard for these assessments, except if inconsistent with any other term of this agreement. Audit scheduling will be based on raw material risk assessment and compliance history for each supplier site.

c. Within the next 24 months, either directly or through its suppliers, NBTY will institute a scientifically and statistically valid material sampling program to confirm authenticity of the covered herbal ingredients based on the applied testing methodologies, including DNA barcoding, where applicable.

4. **Implement Enhanced Measures to Address Food Allergens.**

   a. **Food Allergen Testing.** As soon as practicable, but beginning no later than 12 months from the signing of this Agreement and continuing thereafter, NBTY shall test its herbal finished products (bulk) on no less than an annual basis using the Polymerase Chain Reaction-Enzyme-Linked Immunosorbent Assay (PCR-ELISA) method or other scientifically valid methodology for each of the following allergens: eggs, milk, wheat, soy, and peanut.

   b. **Allergen Labeling:**

      i. Commencing no later than October 1, 2016, NBTY will form an internal committee for the improvement of label text such that all known major allergenic substances appearing in the manufacturing of herbal dietary supplements will appear in terms that can be easily understood by consumers and allow the food-allergic consumer to make an informed choice when selecting such dietary supplement. The committee will propose recommendations for improvements no later than October 1, 2017. These recommendations will be submitted to a major industry group to promote industry-wide improvements.

      ii. NBTY will list all ingredients, including any excipients, on all NBTY labels for Herbal Dietary Supplements, per existing FDA rules.

5. **Improve Consumer Information.** Within the next 24 months commencing October 2016, NBTY will develop educational materials, including scientific content to provide transparency from seed to shelf, including the chemical composition of any extracts, and advise consumers of potential interactions (if any) of the herbs or extracts. These materials will be developed by NBTYs Nutrition and Scientific Affairs Department and will be made via a consumer-facing website and as part of product information fact sheets made available to consumers and to retailers selling NBTY products.

NYAG Assurance of Discontinuance

This agreement constitutes an assurance of discontinuance ("AOD") for purposes of Executive Law § 63(15) that discontinues NYAG's investigation of (1) the NBTY Supplements,

both as to NBTY and to its customers; and (2) NBTY, in connection with the investigation described in the "Background" section above. NBTY has agreed to not sell or return to its customers the specific lots of NBTY Supplements at issue in the investigation, as they have expired or may be needed in connection with certain ongoing litigation. This AOD does not concern, nor does it discontinue NYAG's investigation in connection with, any Tested Supplements not manufactured by NBTY.

Additional Provisions

All terms in this agreement will be in effect for 36 months, will apply to Herbal Dietary Supplements and shall create no rights of enforcement for any third party to the agreement.

NBTY will also prepare a summary report of the activities of the Herbal Authenticity Program with NYAG on a semiannual basis every six months through the term of this agreement. This summary report shall include:

1. The number and species names of ingredients subject to DNA testing used in Herbal Dietary Supplements;
2. The name and address of all facilities in which DNA testing was performed;
3. A list of raw materials rejected or retested as a consequence of the results of DNA testing; and
4. The results of the randomized testing for the allergens specified in Section 4(a) above.

NBTY will, upon request by NYAG, provide any and all additional documentation and information NYAG deems necessary to verify compliance with the terms of this agreement without the necessity for a subpoena.

This agreement is not and shall not be deemed or construed to be an admission of liability by NBTY, or a waiver of any defense that NBTY may have in a dispute with any other party or entity, nor shall it be construed as NBTY's agreement that DNA testing currently is a validated or appropriate method of identity testing of herbal dietary supplements.

Nothing in this agreement shall be construed to require NBTY to take any actions inconsistent with applicable federal and state laws and regulations ("Applicable Law"), to which NBTY is, or in the future, will be subject. Any Applicable Law which conflicts with any provision of this agreement shall supersede the provision with which it conflicts, but only if the conflict is such that compliance with the Applicable Law is impossible without modification of a provision of this agreement. However, in the event NBTY interprets a new Applicable Law as in conflict with the provisions of this agreement, NBTY shall provide reasonable notice to NYAG in writing. In the event that scientific or technological developments identify alternative methodologies to accomplish the purpose of this agreement, NBTY may propose modifications of the procedures herein for consideration by the NYAG. NBTY represents that, to the best of its knowledge upon reasonable inquiry, this agreement and the negotiated terms herein are consistent with Applicable Law as of the effective date of this agreement.

No party shall take any action or make any statement denying, directly or indirectly, the propriety of this agreement. Nothing herein shall limit NBTY, its agents or employees from testifying or asserting any defense in connection with any claims, investigations or litigation arising out of the subject matter of this agreement.

This agreement may not be amended, except by an instrument in writing signed on behalf of all of the parties to this agreement. This agreement may be executed in one or more counterparts, and shall become effective when such counterparts have been signed by each of the parties and exchanged electronically or in hard copy.

This agreement shall be binding on and inure to the benefit of all the parties hereto and their respective successors and assigns, provided that no party other than NYAG may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of NYAG.

Acceptance of this agreement by NYAG shall not be deemed approval by NYAG of any of the practices or procedures referenced in NYAG's findings herein, and NBTY shall make no representation to the contrary.

NBTY's report, as described above, and any other communication to NYAG in connection with this agreement, will be provided to:

The Office of the New York State Attorney General
Attention: Simon G. Brandler
120 Broadway, 25th floor
New York, NY 10271
Simon.Brandler@ag.ny.gov

Any communication to NBTY regarding this agreement will be addressed to:

NBTY, Inc.
Attention: Stratis Philippis
2100 Smithtown Ave
Ronkonkoma, NY 11779
StratisPhilippis@nbty.com

The recipients designated above may be changed by the relevant party by letter or email notice.

NYAG acknowledges NBTY's cooperation through this investigation and has confidence that NBTY's commitments will lead to similar efforts throughout the industry.

Kindly indicate your agreement to the foregoing by signing a copy of this letter agreement and returning the same to me.

Very truly yours,

Eric T. Schneiderman
Attorney General of the State of New York

By: _____
Simon G. Brandler
Senior Advisor & Special Counsel
Executive Division

Agreed to and accepted by:

NBTY, Inc.

By: _____
Title: Steve Cahillane
Chief Executive Officer