



STATE OF NEW YORK  
OFFICE OF THE ATTORNEY GENERAL  
120 BROADWAY  
NEW YORK, NY 10271

ERIC T. SCHNEIDERMAN  
ATTORNEY GENERAL

EXECUTIVE DIVISION

March 27, 2015

Michael G. Archbold, CEO  
GNC Holdings, Inc.  
300 Sixth Avenue  
Pittsburgh, PA 15222

**Re: GNC-Brand Herbal Supplements**

Dear Mr. Archbold,

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

**Background**

In early 2015, NYAG commenced an investigation into the authenticity, purity, and related marketing claims associated with herbal supplements sold in New York State, pursuant to Executive Law § 63(12) and other state laws. This initiative initially focused on four large retailers, including GNC. NYAG commissioned a study (the "NYAG Study") that utilized DNA barcoding to test specific lots of six GNC-brand herbal supplements, including Echinacea, Garlic, Ginkgo Biloba, Ginseng, Saw Palmetto, St. John's Wort, or associated extracts (the "Tested Supplements").

As NYAG detailed in a letter to you, dated February 2, 2015 (the "NYAG Letter"), 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 the presence of a potential allergen in one product. The NYAG Study, and the NYAG Letter that conveyed the results to you, were directed at the presence or absence of the DNA of particular plant species in specified lots of GNC-brand herbal supplements, and did not reach a final determination that the Tested Supplements were fraudulent; the NYAG Letter raised concerns about the measures in place at manufacturers and retailers to ensure the authenticity and purity of herbal supplements.

GNC fully cooperated with NYAG's investigation and removed the affected lots from its stores in New York State. GNC has represented to the NYAG that these lots will be held and are being preserved as proof in connection with consumer lawsuits that arose subsequent to the announcement of our investigation.

NYAG found no evidence in the course of its investigation that GNC deviated from the federal Food and Drug Administration ("FDA") "Current Good Manufacturing Practices" ("cGMPs") rules or standard industry practice in the production of the Tested Supplements. GNC also provided documentation of the scientific testing protocols and quality control methods that GNC employed on the Tested Supplements during production and as finished goods and of subsequent retesting by GNC and an independent laboratory. The results of this testing likewise indicate that the Tested Supplements were manufactured consistent with FDA cGMP requirements.

Where NYAG and GNC disagree, however, is on the sufficiency of federal rules and testing requirements and their relationship to state consumer protections laws. The FDA does not mandate the use of DNA-based technologies, like barcoding, to authenticate herbal supplements. Instead, the FDA allows companies to support their claims through other methodologies, including chemical analysis methods, like those employed by GNC. Given the existence of chemically-similar natural or synthetic substitutes, NYAG is concerned that standard chemical approaches provide inadequate assurance of the authenticity of herbal supplements. With respect to purity, FDA cGMP regulations allow for low levels of inadvertent contamination, including from allergens. NYAG is concerned, however, that there is no federal testing of products manufactured in cGMP facilities to confirm that contamination falls below relevant safety thresholds.

NYAG and GNC agree, however, that DNA barcoding holds great promise for further authentication. GNC has expressed its commitment to use DNA barcoding in its own supply chain, enhance other aspects of its operations, and lead the industry to adopt the same standards.

### **GNC Assurances**

As soon as practicable, but no later than 18 months from the signing of this agreement, GNC will implement source material traceability standards that utilize DNA Barcoding<sup>1</sup> to confirm the authenticity of the "active" herbal/ botanical ingredients<sup>2</sup> prior to extraction, if any, for all GNC Herbal Plus brand products,<sup>3</sup> except in circumstances where no DNA Barcode is available for the relevant species. GNC will implement source material traceability standards utilizing DNA Barcoding for any active herbal/botanical raw material ingredient used in the GNC Herbal Plus brand products as soon as a DNA Barcode becomes available.

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<sup>1</sup> As used in this agreement, the term "DNA Barcode" means a reference sequence of DNA associated with a unique species of plant. "DNA Barcoding" refers to a technique for authenticating organic materials using DNA Barcodes.

<sup>2</sup> As used in this agreement, the "active" herbal/botanical raw material ingredient refers to the plant part or extract identified as coming from the plant listed in the active ingredients on the product label.

<sup>3</sup> As used in this agreement only, the term "GNC Herbal Plus brand products" refers to the GNC Herbal Plus product line, and in addition, other GNC branded dietary supplements that have an herb in the product name.

GNC agrees to contribute any DNA Barcodes, and the scientific methods GNC used to identify such DNA Barcodes, to a publicly accessible database (the "DNA Barcode Library") within the next 24 months for all the active herbal or botanical ingredients used in preparing GNC Herbal Plus products, where those DNA Barcodes are unavailable (either through a public domain source or through a license with a third-party vendor) and do not become available from another source within the 24-month time period.

Within 18 months, GNC will require that all "active" herbal/botanical ingredients used in the GNC Herbal Plus brand product line manufactured and sold in the US be manufactured in cGMP compliant facilities that are certified through a third-party accreditation body, such as ISO, USP, or NSF.

GNC will require that its suppliers implement a randomized allergen testing protocol on all "active" herbal/botanical raw material ingredients used in the GNC Herbal Plus brand product line using a recognized, robust industrial sampling technique (e.g., the square root plus 1 randomized testing protocol) to identify samples for testing. The allergen testing will employ the Polymerase Chain Reaction-Enzyme-Linked Immunosorbent Assay (PCR-ELISA) to detect the eight (8) most common allergens, as defined by FDA.

Using a recognized, robust industrial sampling technique (e.g., the square root plus 1 randomized testing protocol) to identify samples for testing, GNC will test finished products from the GNC Herbal Plus brand product line on an annual basis using a scientifically-validated technique, for the eight (8) most common allergens and to confirm any affirmative representations on the bottle label as to the absence of certain ingredients (e.g., "No sugar").

GNC will prominently display customer-facing signage in all GNC retail locations that explains the difference between whole herbs and extracts using the wording in footnote 4.<sup>4</sup> GNC will make available a template of this signage to any other retailer that sells GNC Herbal Plus brand products.

All product pages on the GNC consumer website for GNC Herbal Plus brand products that are listed as extracts will include in the product description section prominent links to the explanation of the differences between whole herbs and extracts using the wording in footnote 4, and a description of GNC's extraction methods.

GNC will list all ingredients, including all excipients, on all GNC Herbal Plus brand product labels, per existing FDA rules.

On a semi-annual basis and at the conclusion of the term of this agreement, GNC will furnish a report to NYAG providing: (1) the number and species names of active herbal/botanical raw material ingredients used in the GNC Herbal Plus brand product line

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<sup>4</sup> Whole herbs are usually dried, chopped or ground into powder, and may be processed with water or alcohol for encapsulation. Standardized herbal extracts are made by dissolving herbs in a solvent like water, alcohol or liquid carbon dioxide, resulting in a chemical extract. The goal of standardization is to provide uniformity of a specific, constituent that may be biologically active.

sourced after authentication using DNA Barcoding; (2) the name and address of all facilities in which DNA Barcode authentication was performed; (3) a list of materials rejected as a consequence of the results of DNA Barcoding and (4) the results of the randomized testing for the eight most common allergens.

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

#### **NYAG Assurance of Discontinuance**

This agreement constitutes an assurance of discontinuance for purposes of Executive Law § 63(15) that will discontinue NYAG's investigation of GNC Herbal Plus brand products for authenticity, purity, and related labeling issues. NYAG reserves the right to bring an action against GNC related to any other subject. The agreement will be in effect for 36 months, will apply to GNC Herbal Plus brand products sold anywhere in the United States, and shall create no rights of enforcement for any third party, nor be deemed or construed to be an admission of liability by GNC or a waiver of any defense which GNC may have with any other party or entity.

#### **Additional Provisions**

Nothing in this agreement shall be construed to preclude GNC from complying with any Federal legal or regulatory requirement or applicable state law ("Applicable Law"), to which GNC 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 GNC interprets a new Applicable Law as in conflict with the provisions of this agreement, GNC shall provide reasonable notice to NYAG in writing. In the event that scientific or technological developments identify alternative methodologies to accomplish the purposes of this agreement, GNC may propose modification of the procedures herein for consideration by the NYAG.

NYAG has agreed to the terms of this agreement based upon, among other things, the representations GNC and its counsel made to NYAG, NYAG's own investigation, and the documentation furnished by GNC. To the extent that any material representations are later found to be inaccurate or misleading, this agreement is voidable by NYAG in NYAG's sole discretion.

In the event that any one or more of the provisions in this agreement shall for any reason be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this agreement.

This agreement constitutes the entire agreement between NYAG and GNC, and it supersedes all prior agreements and understandings, written or oral, among the Parties with respect to the subject matter of this agreement. No representation, inducement, promise, understanding, condition, or warranty not set forth in this agreement has been made to or relied upon by any party in agreeing to 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 GNC, 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 GNC shall make no representation to the contrary. GNC's report, as described above, and any other notice in connection with this agreement, will be provided to:

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

Any communication between us regarding this matter will be addressed to:

GNC  
Attention: Jim Sander  
300 Sixth Avenue  
Pittsburgh, PA 15222  
Jim-Sander@gnc-hq.com

With a copy to:

Stuart Shorenstein, Esq.  
Cozen O'Connor  
277 Park Avenue  
New York, NY 10072  
sshorenstein@cozen.com

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

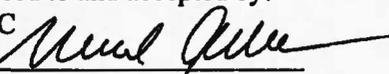
NYAG acknowledges GNC's cooperation through this investigation and hopes that GNC's commitments will lead to similar efforts throughout the industry and further broad reform.

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:  
GNC  
By   
Title CEO