



U.S. Department of Justice
Consumer Protection Branch

Abbe David Lowell, Esq.
Chadbourne & Parke, LLP

Re: GNC Holdings, Inc.

Dear Mr. Lowell:

The United States Attorney's Office for the Northern District of Texas and the United States Department of Justice, by and through the Consumer Protection Branch, and the Food and Drug Administration ("FDA") (collectively, "the Government"), have taken a number of important enforcement actions to address concerns with the safety, purity and potency of dietary supplements. These actions have included the filing of criminal cases, civil proceedings, and regulatory/administrative actions. The Government is not taking these actions against GNC Holdings, Inc. ("GNC"), but enters into this non-prosecution agreement with GNC in furtherance of those actions.

The Government has been conducting a criminal investigation (the "Investigation") into USP Labs, LLC (hereinafter, "USP Labs") for the alleged violation of laws, including but not limited to, the Federal Food, Drug, and Cosmetic Act ("FDCA"), relating to sales of certain USP Labs dietary supplements, including but not limited to OxyElite Pro, Jack3d, and VERSA-1. During the course of the Investigation, the Government uncovered sufficient evidence to conclude that USP Labs provided false information, false assurances and fake documentation to third parties, including GNC, about the ingredients being used in its products. The Investigation also determined the facts set forth on Attachment A to this agreement, incorporated herein by reference, and GNC has accepted responsibility for its conduct described therein.

On the understandings contained in this agreement, the Government agrees to close any active inquiries affecting GNC presently pending relating to the USP Labs products discussed above without the filing of any action. The Government enters into this agreement based, in part, on the following factors: (1) GNC's acceptance of responsibility for its conduct; (2) GNC's cooperation in this matter, including its providing the Government with information about the conduct of individuals within and outside of GNC; (3) GNC's commitment to voluntary compliance measures, described below; (4) GNC's having voluntarily undertaken organizational changes with respect to its sale of dietary supplements; (5) GNC's payment of a money sum, described below; and (6) GNC's commitment to fulfill all of the terms of this agreement. GNC expressly understands that this agreement does not preclude the filing of a case related to any other subject.

GNC does not endorse, ratify or condone illegal conduct related to the manufacture, distribution or sale of dietary supplements. GNC states that it has accordingly entered into this agreement for the benefit of consumers, state and federal regulators, and the broader dietary supplement industry (including raw material suppliers, manufacturers and retailers). As set forth

below, GNC has agreed to take certain compliance steps, which it believes and has represented to the Government are designed to provide greater assurance of dietary ingredient and dietary supplement safety, help ensure compliance with the laws and regulations relating to dietary supplements, better ensure expedited removal of products that should not be sold, and help prevent illegal products and ingredients from entering the market.

GNC Voluntary Compliance Commitments

GNC and the Government agree that GNC shall undertake the following voluntary compliance measures. These steps are intended to help prevent illegal ingredients from entering the market.

1. Upon learning of the issuance of any public written notice of the FDA to industry, any company, or any individual, or upon public written notice to GNC directly, wherein the FDA has indicated its belief that any purported dietary supplement or any ingredient in a purported dietary supplement is not legal under federal law and/or is not safe (“FDA public written notice” means an FDA Warning Letter to any company, the issuance of an FDA Public Health Advisory, or the commencement of legal action by the Department of Justice asserting such conclusion), GNC will take immediate actions to suspend the sale of such product or products known to contain the ingredient, and will place the ingredient on the “Restricted List” as described in paragraph 2. GNC has already voluntarily begun to implement this approach in particular instances, as the following demonstrate:
 - a) On April 23, 2015, FDA issued Warning Letters to several companies, not including GNC, stating that the ingredient known as BMPEA (and its name variations) is not a dietary ingredient pursuant to section 201(ff)(1) of the FDCA and requesting that those companies receiving the letters immediately cease distribution of any dietary supplement products containing BMPEA as a dietary ingredient. GNC immediately and voluntarily stopped its sales of products containing BMPEA, all of which were third-party products, and GNC in this agreement agrees not to knowingly sell products containing the ingredient BMPEA (or its known name variations).
 - b) On September 28, 2015, an FDA official signed a Declaration that was later filed in Oregon state court stating that the ingredient picamilon (and its name variations) is not a dietary ingredient pursuant to section 201(ff)(1) of the FDCA. GNC was forwarded a copy of that Declaration on September 29, 2015 and immediately and voluntarily stopped its sales of products containing picamilon, all of which were third party products, and GNC in this agreement agrees not to knowingly sell products containing the ingredient picamilon (or its known name variations).
 - c) On March 31, 2016, FDA issued Warning Letters to several companies, not including GNC, stating that the ingredient known as methylsynephrine (and its name variations) is not a dietary ingredient pursuant to section 201(ff)(1) of the FDCA and requesting that those companies receiving the letters immediately cease distribution of any dietary supplement products containing methylsynephrine as a dietary ingredient. GNC immediately and voluntarily

stopped its sales of products containing methylsynephrine, all of which were third-party products, and GNC in this agreement agrees not to knowingly sell products containing the ingredient methylsynephrine (or its known name variations).

2. GNC will maintain and continuously update a list of ingredients that will be prohibited from inclusion in any products that are sold by GNC. This “Restricted List” will include all ingredients identified by any FDA public written notice. Vendors selling products to GNC for the sale of such products by GNC will be required to affirmatively certify to GNC that the products being sold to GNC do not contain ingredients that are on the Restricted List. This representation will be included in the amendment to the vendor agreement discussed in item (7), below. GNC will amend or update the Restricted List immediately upon any FDA public written notice as such notice is described herein. GNC may remove an ingredient placed on the Restricted List as a result of an FDA public written notice only if (a) the FDA public written notice related to the product or ingredient did not concern the safety of the product or ingredient, and (b) GNC believes and documents that the product or ingredient meets the criteria set forth in paragraph 6 for inclusion on the Positive List. The Restricted List, as amended or updated, will be available for review by all of GNC’s vendors on its internet-housed vendor portal. GNC agrees that the Restricted List does not have the force or effect of law or constitute a list of illegal ingredients under the FDCA now or in the future; rather, GNC will create and use the list voluntarily to assist it in keeping products it does not want to sell off of its shelves.
3. Along with the Restricted List, GNC will develop and maintain a list of dietary ingredients that GNC believes comply with the applicable provisions of the FDCA. This “Positive List” will be utilized by GNC to determine whether and to what extent the purported dietary ingredients listed in a product require additional review before the product can be sold. GNC agrees that the Positive List does not have the force or effect of law, constitute a list of permitted dietary ingredients under the FDCA, or confer lawful status on any dietary ingredient now or in the future; rather, GNC will create and use the list voluntarily to assist it in keeping products it does not want to sell off of its shelves.
4. Before GNC markets a dietary supplement product containing an ingredient that GNC has not previously sold, GNC will review that ingredient to evaluate whether the ingredient is on the Restricted List or, if the ingredient is a dietary ingredient, whether it is on the Positive List.
5. If the ingredient is on the Restricted List, then GNC will not approve that product for sale.
6. GNC will only sell dietary supplements containing dietary ingredients on the Positive List. If the dietary ingredient is on the Positive List, then it is available to be sold by GNC under its procedures. However, a purported dietary ingredient that is not on the Positive List may qualify for inclusion on the Positive List if the vendor confirms to GNC’s satisfaction that (a) the purported dietary ingredient is a legal ingredient and a dietary ingredient under the terms of the FDCA; (b) the product as a whole complies with

the FDCA; and (c) GNC is satisfied by GNC's own research and consultation with outside food and drug counsel, when needed, that the purported dietary ingredient to be added to the Positive List is a legal dietary ingredient under the terms of the FDCA. In addition, GNC has noted that a proposed Industry Product Notification Database may be established, and this review process may be streamlined for increased efficiency through use of that database on the written agreement of the parties when and if such a database becomes operational.

7. GNC is committed to substantially revising its own approach to its vendors of third party products through the following voluntary initiatives: to improve vendor focus on compliance with the legal standards for dietary ingredients in dietary supplements, including for new dietary ingredients (NDIs), as well as compliance with dietary supplement GMPs; to set specific vendor certifications for compliance with applicable federal legal requirements by vendors and to require regular updates of certifications; and to assure that applicable dietary ingredient and GMP requirements are met. Within ninety (90) days of execution of this agreement, GNC will issue a letter to each of its dietary supplement vendors reemphasizing the vendors' commitment in GNC contracts to provide lawful and otherwise compliant products and their need to ensure that all current and future products comply with the FDCA, and requesting that each vendor review each of its products currently being sold to GNC to verify compliance with the FDCA. Accompanying this letter will be an amendment to GNC's vendor agreement, whereby the vendor will be required to explicitly warrant the following with regard to each of its dietary supplements sold to GNC:
 - a) The dietary supplement contains only legal dietary ingredients pursuant to the terms of the FDCA, 21 U.S.C. § 321(ff).
 - b) Any "new dietary ingredient" that is not exempt from notification under the FDCA has been properly notified to FDA no less than 75 days prior to marketing, pursuant to the FDCA, 21 U.S.C. § 350b.
 - c) Every ingredient that is not a dietary ingredient is either generally recognized as safe or is an approved food additive pursuant to the FDCA, 21 U.S.C. §§ 321(s) and 348.
 - d) All ingredients in the product are identified on the product label in accordance with FDA statutory and regulatory requirements.
 - e) For every product shipment to GNC, the product at the time of shipment will not contain any ingredient listed in GNC's then-current Restricted List, made available on its vendor portal.
 - f) The facilities used in the manufacturing of the dietary supplements sold to GNC are in substantial compliance with all current Good Manufacturing Practice regulations requirements in 21 CFR Part 111.

8. GNC will amend its purchasing agreements to provide GNC with the unilateral right to limit, restrict or discontinue the use of promotional money (i.e., monetary incentives provided to GNC employees to sell particular products at GNC stores) at any time or for any reason. GNC agrees that, within 120 days from the effective date of this agreement, it will discontinue promotional money with any product containing ingredients not on the Positive List. Furthermore, when and if industry-wide certification processes are adopted that include an official quality seal, GNC will not use promotional money with any third-party product that does not bear the official quality seal.

9. To strengthen GNC's current Adverse Event Report ("AER") policy, GNC will update its training modules for its retail store employees relating to the handling of adverse event reports received from customers. This field training module will include, among other things, instructions on how to collect the information required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act from customers reporting adverse events related to dietary supplement products sold by GNC. Each retail store employee will be required to complete the training twice per year.

Additional Provisions

GNC's obligations under this agreement will have a term of sixty (60) months from the date that all parties have signed this agreement (the "Effective Date"). GNC's obligations under this agreement do not modify or absolve it from any prospective obligation to comply with the FDCA or its implementing regulations or any other federal law.

It is understood that, in the event the Government determines, in its sole discretion, that GNC has materially violated any provision of this agreement, an extension or extensions of the term of this agreement may be imposed by the Government, in its sole discretion, for up to a total additional period of one year, without prejudice to the Government's right to proceed as provided below. Any extension of this agreement extends all terms of this agreement for an equivalent period.

Notwithstanding anything to the contrary in this agreement, it is understood that beginning thirty-six (36) months after entering into this agreement, GNC may petition the Government for an early termination of the agreement of up to one year. The Government agrees to evaluate in good faith any request for early termination, taking into account GNC's compliance with this agreement and any other factors that the Government deems relevant. GNC acknowledges that the Government has discretion to grant or deny the request and that the Government is under no obligation to grant an early termination or to explain its reasoning denying a request for early termination.

It is understood that GNC will comply in a timely manner with all of the terms of this Agreement, including the maintenance, or as necessary, the establishment, of the enhanced compliance measures described above. If GNC sells, merges, or transfers all or substantially all of its business operations, GNC will maintain its ability to fulfill all of its obligations under this agreement, or include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest, to fulfill all of GNC's obligations under this agreement.

Until the date upon which all investigations and any prosecution arising out of the conduct described in this agreement are concluded, whether or not they are concluded within the term of this agreement, it is understood that GNC will: (1) cooperate fully with the Government and any law enforcement agency designated by the Government regarding matters arising out of the conduct covered by this agreement; (2) use its best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of GNC at any meeting or interview or before the grand jury or at any trial or other court proceeding regarding matters arising out of the conduct covered by this agreement; and (3) truthfully disclose to the Government all factual information, documents, records, or other tangible evidence not protected by a valid claim of privilege or work product regarding matters arising out of the conduct covered by this agreement about which the Government or any designated law enforcement agency inquires. This paragraph does not apply to any future investigation of, or filing of any case against, GNC.

GNC has represented to the Government that the enhanced compliance measures contained in this agreement are consistent with GNC's efforts in 2015 and 2016 to enroll a broad group of companies from different sectors of the industry to adopt new elevated industry standards, including full traceability of ingredients along the supply chain. Specifically, GNC also has represented to the Government that these industry efforts have called for: (1) harmonized audit standards, and required annual inspections of dietary supplement manufacturing facilities by qualified, independent third party organizations that would certify whether or not the facility meets current Good Manufacturing Practices (cGMPs), based on 21 CFR Part 111; (2) strengthened quality and integrity in the botanical raw materials supply chain by developing and establishing industry Good Agricultural and Collection Practices and GMPs for the botanical raw materials from farm to facility, including traceability standards and testing requirements for raw material producers, brokers and distributors; and (3) adoption of an effective and efficient industry-sponsored product database with a unique product number issued for each registered dietary supplement product. GNC has further represented to the Government that these new standards are intended to improve: (1) quality, purity, integrity and safety of dietary supplement products; (2) regulatory compliance with respect to raw materials, manufacturing and finished goods; and (3) credibility, stability and integrity in the supplement industry. The Government takes no position on these industry efforts.

To further the industry initiatives described above, GNC is voluntarily developing, at its own expense, training guidelines, implementation checklists and video scripts in English and three other languages for farmers to learn and then implement elements critical to food safety, traceability and chain of custody, as part of Good Agricultural Practices in their role in adhering to these botanical GMPs and to further the establishment of a product database. GNC has committed to these industry initiatives and will commit at least \$500,000 over the term of this agreement, beginning in 2016, for these efforts.

It is understood that, if the Government in its sole discretion determines that, during the term of this agreement, GNC has (1) committed any violation of 21 U.S.C. § 331 with intent to defraud or mislead pursuant to 21 U.S.C. § 333(a)(2) relating to the adulteration or misbranding of its products after the Effective Date of this agreement; (2) committed any felony under United States federal law after the Effective Date of this agreement; (3) provided deliberately false, deliberately incomplete, or deliberately misleading information at any time in connection with

this Agreement; or (4) otherwise materially violated any provision of this agreement, GNC will thereafter be subject to civil and/or criminal proceedings for any violation of federal law about which the Government has knowledge, including perjury and obstruction of justice. It is understood that any such proceeding that is not time-barred by the applicable statute of limitations on the Effective Date of this agreement, including time protected as the result of existing agreements between GNC and the Government to toll the applicable statute of limitations, may be commenced against GNC, notwithstanding the expiration of the statute of limitations during the term of this agreement plus six months. Thus, GNC agrees that the statute of limitations with respect to any such proceeding that is not time-barred as of the Effective Date of this agreement will be tolled for the term of this agreement plus six months.

It is further understood that any testimony given by or on behalf of GNC before a grand jury, any court or tribunal, whether before or after this agreement, and any leads derived from such statements, will be admissible in evidence in any and all proceedings brought by the Government pursuant to this agreement against GNC; and GNC and its counsel will stipulate that this Agreement may be read to the jury or other finder of fact in whole or in part, as elected by the Government.

In the event that the Government determines that GNC has materially breached this agreement, the Government agrees to provide GNC with written notice of such breach prior to instituting any proceeding resulting from such breach. GNC will, within thirty (30) days of receipt of such notice, have the opportunity to respond to the Government in writing to explain the nature and circumstances of the purported breach, as well as the actions GNC has taken to address and remediate the situation, if any, including whether GNC believes a breach occurred, whether such breach was material, and whether such breach was knowing or willful. The Government agrees to consider GNC's explanation in determining whether to institute a proceeding.

Whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of GNC will be imputed to GNC for the purposes of determining whether GNC has violated any provision of this Agreement, will be at the sole discretion of the Government, applying standards consistent with applicable law. If the Government determines that GNC has breached this Agreement, it is understood that, as a contractual remedy, the Government may, at its sole discretion, impose a monetary payment of up to \$10,000 per day for each day GNC is in breach of the Agreement ("Stipulated Penalties"). The imposition of such Stipulated Penalties will be in the alternative to instituting a proceeding due to a breach of this Agreement. The Government will notify GNC in writing of GNC's failure to comply and the Government's exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter will set forth: (a) the provision breached; (b) the date of the breach; (c) a description of the breach sufficient to permit GNC to cure (as described below); and (d) the amount of Stipulated Penalties claimed by the Government as of the date of the Demand Letter.

It is further understood that within thirty (30) days after receiving the Demand Letter, or such longer period as the United States may agree in writing, GNC will cure the breach to the Government's reasonable satisfaction ("Cure Period"). If GNC cures the breach within the Cure Period, no Stipulated Penalties will be due. If GNC fails to cure the breach during the Cure

Period, Stipulated Penalties calculated from the date of breach to the date of payment will be immediately payable to the United States. The Stipulated Penalties will be paid by electronic fund transfer according to wire instructions that will be provided by the Government. The U.S. Attorney's Office for the Northern District of Texas and the Department of Justice's Consumer Protection Branch will make a joint reasonable determination regarding GNC's failure to comply with any of the obligations described in this Agreement, and that decision will be final and non-appealable. It is understood that the United States District Court for the Northern District of Texas will have jurisdiction over any action to collect a Stipulated Penalty.

It is understood that GNC has agreed to pay the sum of two million two hundred fifty thousand dollars (\$2,250,000.00) to the United States, payable before December 31, 2016. This payment is final and will not be refunded. GNC will pay the amount by wire transfer according to the wire instructions provided by the Government. It is understood that nothing in this Agreement constitutes an agreement by the Government that this amount is the maximum payment that may be imposed in any future action in the event of a breach of this Agreement, and that the Government is not precluded from then arguing or presenting evidence in any future action that the Court should impose a higher payment. However, it is further understood that in the event of a future prosecution due to a breach of this Agreement, the Government agrees that it will recommend to the Court that any amount paid by GNC under this Agreement should be offset against any fine that the Court might impose as part of a future judgment and conviction.

It is understood that within ten (10) business days of the Effective Date of this Agreement, GNC will communicate to all GNC employees that GNC has entered into this Agreement and make available this Agreement to all such employees, including translations of this Agreement where appropriate for non-English speaking employees. It is further understood that GNC and the Government may disclose this Agreement to the public.

It is understood that this agreement is binding on GNC, the Office of the United States Attorney for the Northern District of Texas, and the Consumer Protection Branch of the United States Department of Justice.

Any notice to the Government under this agreement will be given by personal delivery, or overnight delivery by a recognized delivery service addressed to the following:

Chief, Criminal Division
U.S. Attorney's Office,
Northern District of Texas
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699

Director, Consumer Protection Branch
U.S. Department of Justice
450 5th St NW Room 6400 South
Washington, DC 20001

Any notice to GNC under this Agreement will be addressed to the following:
GNC Holdings, Inc.
Office of the Chief Legal Officer
300 Sixth Avenue
Pittsburgh, Pennsylvania 15222

This agreement sets forth all the terms of the agreement between GNC and the Government. No amendments, modifications, or additions to this agreement will be valid unless they are in writing signed by the Government, the attorneys for GNC, and a duly authorized representative of GNC.

SIGNATURES FOR THE UNITED STATES GOVERNMENT

BENJAMIN C. MIZER
Principal Deputy Assistant
Attorney General
Civil Division
U.S. Department of Justice

JOHN R. PARKER
United States Attorney
Northern District of Texas

MICHAEL S. BLUME
Director
Consumer Protection Branch
U.S. Department of Justice




ERRIN MARTIN
Assistant United States Attorney
Northern District of Texas



DAVID SULLIVAN
PATRICK R. RUNKLE
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice

Approved by:



CHAD E. MEACHAM
First Assistant United States Attorney
Northern District of Texas

OF COUNSEL:
MARGARET M. DOTZEL
Acting General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

NATHAN SABEL
Associate Chief Counsel
United States Department of Health and Human Services
Office of the General Counsel

DATE: 12/7/2016


SIGNATURE FOR GNC HOLDINGS, INC.



JAMES M. SANDER
Chief Legal Officer

DATE: 12/5/16

SIGNATURE OF COUNSEL FOR GNC HOLDINGS, INC.



ABBE DAVID LOWELLE
Chadbourne & Parke, LLP
Counsel for GNC Holdings, Inc.

DATE: 12/6/16

FACTUAL RECITATION

The investigation conducted by the Government to date has determined the facts set forth below. GNC accepts that it is responsible for its acts as described herein.

1. The first formulation of Jack3d and OxyElite Pro purchased by GNC from USP Labs contained an ingredient, 1,3-dimethylamylamine (“DMAA”). During June 2013, the Government instituted actions in several federal courts in the United States to seize OxyElite Pro containing DMAA. As a result of those actions, GNC destroyed large amounts of OxyElite Pro that it had been storing in anticipation of sale. The second formulation of OxyElite Pro, and the first and only formulation of VERSA-1, was pulled from the market when USP Labs recalled the product in November 2013.
2. In August 2013, GNC purchased OxyElite Pro Advanced Formula from USP Labs, the third formulation of the product. For OxyElite Pro Advanced Formula, as well as the prior USP Labs Products, GNC relied on representations from USP Labs that ingredients contained in these products complied in all respects with the FDCA and applicable state laws. GNC did not undertake additional testing or require additional verified certifications to confirm the representations made by USP Labs and verify that the ingredients in OxyElite Pro Advanced Formula were as represented.
3. The Government has determined that OxyElite Pro Advanced Formula’s product label listed an ingredient, cynanchum auriculatum root extract; that was not contained in the product. Evidence obtained during the Investigation demonstrates that USP Labs purchased purported ground cynanchum auriculatum roots from China and mislabeled the product as an extract in order to save money. This evidence shows that USP Labs also took advantage of scientific research describing potential health benefits of certain components of cynanchum auriculatum root extract that would have been present only in miniscule quantities (if at all) in the ground roots. Evidence further shows internal concern on the part of USP Labs’ scientific consultant that cynanchum auriculatum could cause “liver toxicity,” due to a publicly available scientific paper describing potential toxicity problems with cynanchum auriculatum.
4. GNC was unaware of this information because it did not manufacture those products, did not perform an independent evaluation of the ingredients of OxyElite Pro Advanced Formula and had no knowledge of USP Labs’ conclusions regarding cynanchum auriculatum. However, at all relevant times, GNC had a written “guarantee” from USP that the products it was selling to GNC complied in all respects with the FDCA. GNC has represented to the Government that it did not sell any of these products knowing that such product violated the FDCA.