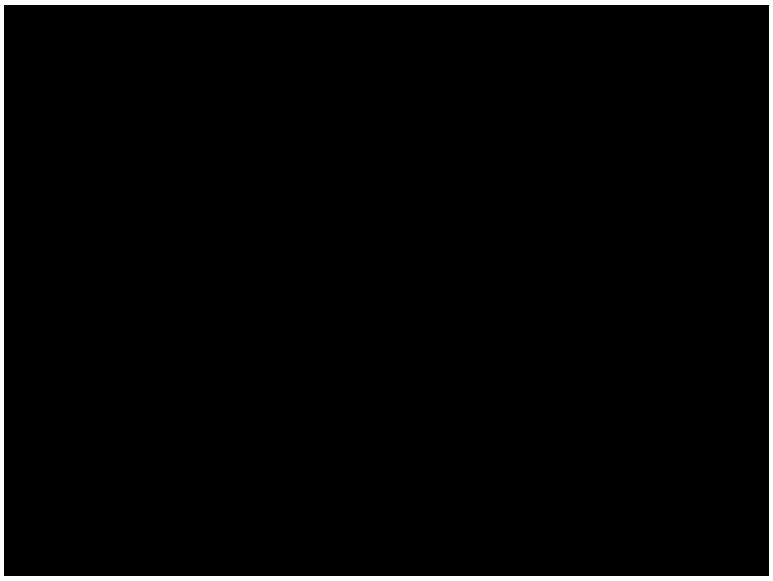
A.G. Schneiderman Announces Agreement With GNC To Implement Landmark Reforms For Herbal Supplements

GNC To Use DNA Barcoding To Authenticate Plants Used In Supplements; Adopt New Testing Standards To Prevent Contamination; Improve Transparency For Consumers

Reforms – Which Exceed FDA Standards — Follows A.G. Investigation That Found Majority Of Tested Supplements Didn't Contain DNA From Listed Plant

Schneiderman: I Urge All Herbal Supplements Manufacturers And Retailers To Join GNC In Working With Us To Ensure Consumer Safety



NEW YORK – Attorney General Eric T. Schneiderman today announced a landmark agreement with Pennsylvania-based retail giant GNC to implement new standards in authenticating herbal supplements, ensuring their purity, and educating consumers about their chemical content. Under today's agreement, GNC will perform DNA barcoding on the "active" plant ingredients used in its products; implement testing for contamination with allergens, both before and after production; and post prominent signage advising consumers of the processed, chemical nature of extracts. GNC will be required to implement these new procedures in all of its more than 6,000 stores nationwide, making this agreement the first in the nation to require testing standards for herbal supplements that exceed current FDA requirements.

"When consumers take an herbal supplement, they should be able to do so with full knowledge of what is in that product and confidence that every precaution was taken to ensure its authenticity and purity," said **Attorney General Schneiderman**. "When it comes to consumer health, we expect companies to reach a high safety bar. Without tests and safeguards, including those that rule out dangerous allergens, these supplements pose

New York City Press Office (212) 416-8060

Albany Press Office (518) 776-2427

nyag.pressoffice@ag.ny.gov

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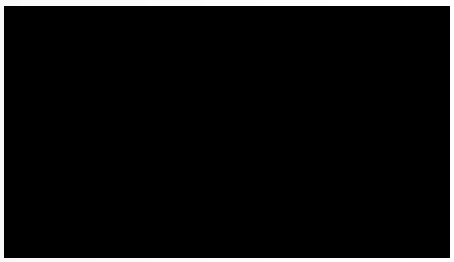


A.G. Outlines Impact Of Spectrum-Time Warner Cable's Alleged Fraud In Western Issues Consumer Alert To Assist New Yo In Choosing The Best Internet Service

unacceptable risks to New York families. I urge all herbal supplements manufacturers and retailers to join GNC in working with my office to increase transparency and put the safety of their customers first."

Last month, Attorney General Schneiderman sent cease-and-desist letters to GNC, Target, Walgreens and Walmart, after a study commissioned by his office failed to detect identifiable genetic material for the plants depicted on the labels in most of the four retailers' herbal supplement products. The study further detected DNA associated with plants not listed on the labels, as well as the presence of potential allergens. In launching his investigation, the Attorney General raised concerns about the measures put in place by manufacturers and retailers to ensure the authenticity and purity of herbal supplements – which are taken by more than half of all American adults – and the sufficiency of federal standards regulating this $60 billion worldwide industry. Earlier this month, joined by the Connecticut and Indiana state attorneys general and the Puerto Rico Secretary of Consumer Affairs, Attorney General Schneiderman formed a coalition to further investigate the business practices of the herbal supplement industry.

"This agreement provides stronger consumer protections for these GNC supplements and highlights the relative weak federal standards," said **Indiana Attorney General Greg Zoeller**, whose office is not party to today's agreement but is part of the multistate coalition. "Hopefully this will lead others in the supplement industry to follow suit and encourage the FDA to review the existing national standards that are currently in place that has resulted in attorneys general making efforts to ensure better consumer protections for dietary and herbal supplements."

"Consumers should be able to expect that the product they are purchasing actually contains the ingredients that are listed on the label," said **Connecticut Attorney General George Jepsen**. "GNC has taken a laudable step toward ensuring the highest level of transparency in the products it offers to consumers. The testing and disclosures included in this agreement are truly landmark and will provide important information about these products to consumers in New York, Connecticut and across the country so that they can make educated decisions when choosing to use a supplement. I commend Attorney General Schneiderman for his continued leadership on this issue."

"GNC and the NY Attorney General's office are to be congratulated for so promptly reaching agreement on the means of providing monitoring of herbal supplements so as to more effectively ensure safety of consumers who purchase these products," said **Arthur P. Grollman, M.D., Professor of Pharmacological Sciences at Stony Brook University**. "This agreement should serve as a model for other companies and, hopefully, for the federal government to enact similar regulations. Adoption of DNA barcoding to confirm the authenticity of all plants prior to processing is a major step forward in the regulation of herbs."

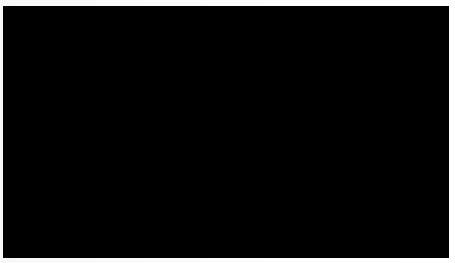
New York State Assembly Assistant Speaker Felix W. Ortiz said, "Protecting health & safety of New Yorkers is always important. This agreement insures that consumers know what they are buying and that the product quality is guaranteed. I applaud the Attorney General for his initiative."

David Schardt, Senior Nutritionist, Center for Science in the Public Interest said, "The agreement GNC reached with New York State represents important progress in ensuring that supplements contain what they claim to. But Congress should pass reform that would allow the FDA to police this marketplace and remove products that are dishonestly marketed or potentially dangerous.

Jane L. Delgado, President and CEO of the National Alliance for Hispanic Health said, "All consumers deserve to know that what is on the label is actually in the supplements they are using. It is time for all manufacturers to adopt higher standards of DNA technologies to ensure authenticity of components and strict testing for contaminants."

David S. Seres, M.D., Director of Medical Nutrition at Columbia University Medical Center said, "When federal law prohibits the kind of regulation that we demand on all other products used for health benefits, the Attorney General's actions represent an

A.G. Schneiderman Announces Lawsuit Agair Spectrum-Time Warner Cable And Charter Communications For Allegedly Defrauding New Yorkers Over Internet Speeds And Performance



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important step in reining in the supplement industry and assuring that the consumer can trust what is in the bottle."

Tod Cooperman, M.D., President of ConsumerLab.com said, "FDA's rules focus on making sure a supplement is produced the same way each time, but not necessarily with high-quality, authentic ingredients. Companies are allowed to choose their own tests and set their own standards. The additional tests outlined by this agreement are a positive step toward making sure that herbal supplements are actually made from the plants on their labels."

Josh Bloom, Director of Chemical and Pharmaceutical Science, American Council on Science and Health said, "Although this agreement is certainly an improvement from the standards that have been in place, and Attorney General Schneiderman should be applauded for his work in this area, this is only the first step. Congress has stripped the FDA of the ability to approve or reject these products, which are essentially unregulated drugs."

While the Attorney General's Office found that GNC's herbal supplements were produced in compliance with FDA regulations requiring the use of current good manufacturing practices, the investigation raised questions regarding the sufficiency of those requirements in relation to state consumer protection laws.

For instance, 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. Given the existence of chemically-similar natural or synthetic substitutes, the Attorney General's Office remains concerned that these alternate methodologies do not provide adequate assurances of the authenticity of herbal supplements. Current FDA regulations allow for low levels of inadvertent contamination, including from allergens, and there is no federal testing required to confirm that contamination falls below relevant safety thresholds.

Contamination in herbal supplements could pose a significant danger to those who have food allergies or take medication – and there have been a number of examples of supplements endangering consumer safety. A 2013 outbreak of hepatitis that struck at least 72 people in 16 states was traced to a tainted supplement. Last October, an infant at a Connecticut hospital died when doctors gave the child a popular probiotic supplement that was later found to be contaminated with yeast.

DNA barcoding is a technique used to authenticate organic materials using unique reference sequences of DNA, which holds great promise as a scientific technique for the verification of plant species. GNC will commit to implementing this procedure during herbal supplement production, enhancing other aspects of its operations, and leading the industry to adopt the same standards, as follows:

Authentication: Within 18 months, GNC will begin utilizing DNA barcoding to confirm the authenticity of all plants used as sources for its herbal supplements products prior to processing. This will ensure the presence of a biological connection between the source plant and the extract that is eventually included in GNC's supplements. In cases where no DNA barcode is yet available for the relevant species, GNC has committed to perform its own sample collection – DNA isolation and sequencing – to create a DNA barcode for that plant ingredient. GNC will contribute any new barcodes, and the scientific methods used to identify them, to a publicly accessible database within 24 months.
GNC will also require that all herbal ingredients used in its products are manufactured in facilities that are certified as good manufacturing compliant by a third-party accreditation body, such as ISO, USP, or NSF.

Broad Testing For Contaminants: GNC will implement a sweeping, randomized testing protocol for the eight most common allergens – defined by the FDA as milk, eggs, peanuts, tree nuts, fish, shellfish, soy and wheat. This will include testing certain raw ingredients for contamination and, after production, ensuring that those allergens are not present in its products. In order to do this, GNC will not only require its suppliers to implement this testing protocol, but will also perform testing themselves on finished products, using a scientifically-validated technique. In addition, GNC will also conduct testing to confirm any affirmative

representations on its labels that particular ingredients are absent from certain products (e.g. "No sugar.")

Consumer Transparency: GNC will prominently display signs in stores across the country and include language on its website indicating whether a supplement product is derived from whole herbs or extracts and explaining the difference between those two processes. In particular, these signs will highlight that extracts are chemicals derived from plants after applying solvents, like liquid carbon dioxide. GNC will list all ingredients used in its products on its labels, per existing FDA rules.

Reporting: GNC will provide semiannual reports to the Attorney General's Office, detailing all plant species sourced after authentication using DNA barcoding; the name and address of all facilities in which DNA barcode authentication was performed; a list of materials rejected as a consequence of the results of the barcoding and the results of the randomized testing for common allergens. GNC will provide additional documentation and information necessary for the Attorney General's Office to verify compliance with this agreement without the necessity for a subpoena.

In response to the Attorney General's cease-and-desist letter, GNC removed from its shelves all products that the office's testing found to contain contaminants not identified on their labels. As described in the agreement, those products remain off of store shelves.

The case is being handled by Executive Deputy Attorney General Marty Mack, Senior Adviser and Special Counsel Simon Brandler and Assistant Attorney General Deanna Nelson, Assistant Attorney General Alicia Lendon, Assistant Attorney General Richard Yorke and Environmental Scientist John Davis.

The broader investigation into the herbal supplements industry is being handled by Assistant Attorney General Dorothea Caldwell-Brown, Research Analyst John Ferrara, Research Director Lacey Keller, Chief of the Environmental Protection Bureau Lemuel Srolovic and Executive Deputy Attorney General for Economic Justice Karla Sanchez.

To see the copy of the agreement, click here.

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