

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

STATE OF INDIANA
OFFICE OF THE ATTORNEY GENERAL
302 W. WASHINGTON ST., 5TH FLOOR
INDIANAPOLIS, IN 46204

May 26, 2015

VIA FASCIMILE AND EMAIL

Dr. Stephen Ostroff, Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Ostroff:

We write to urge the Food and Drug Administration to overhaul federal oversight of the dietary supplement industry, including by promulgating enhanced Dietary Supplement Current Good Manufacturing Practices (“CGMP”) regulations.¹ On May 14, 2015, the Organic and Natural Health Association, a dietary supplement trade group, submitted a citizen petition requesting that FDA extend CGMP rules to cover dietary ingredient suppliers. Not only should FDA swiftly act on this request, the agency should view the petition as an opportunity to broadly revisit and strengthen the existing supplement regulations and their enforcement.

By exercising the agency’s rulemaking authority, FDA can independently achieve certain vitally-needed reforms. FDA should act without delay.

The quality control and safety issues facing the dietary supplements industry are a matter of grave public concern. Scientists and consumer advocates have repeatedly discovered dangerous natural and synthetic compounds, including powerful stimulants, anabolic steroids, and prescription drugs, in commercially available dietary supplements.² Using various scientific techniques, experts have exposed adulteration and substitution across a range of herbal supplements, from American ginseng and saw palmetto, to bilberry, skullcap, and black cohosh. Separate studies have further shown that unlisted fillers and contaminants, including allergens, dangerous pesticides, heavy metals, and solvents, are a persistent problem.

Earlier this year, the Office of the New York Attorney General launched an initiative to probe the business practices of the dietary supplements industry. This has included investigating the purity and authenticity of certain popular herbal supplements using a DNA barcoding technique, analyzing the label claims and advertising of particular supplement manufacturers and retailers, reviewing quality control and testing procedures across the industry, and conferring with a range of experts, including from FDA, the supplement industry, consumer advocates, and the scientific and medical communities. Aided by a coalition of attorneys general led jointly by New York and Indiana, these steps have reinforced past research and findings about the serious

¹ The CGMP regulations are found at 21 C.F.R. Part 111.

² This includes the recent discovery that—more than a year after FDA first raised concerns—products containing the amphetamine-like chemical BMPEA remain on store shelves.

quality control issues facing the industry and raise further questions about the measures in place to protect the physical health and financial well-being of the millions of American consumers who regularly buy dietary supplements.

Our initiative has benefited greatly from technical guidance from FDA. Although our effort remains in its early stages, we have observed several serious flaws in the CGMP rules and their enforcement:³

First, in promulgating the CGMP rules, FDA elected not to cover ingredient suppliers, raising questions about the integrity of the dietary supplement supply chain. Excluding suppliers from existing regulations is all the more concerning given that manufacturers typically receive ingredients as unrecognizable vats of powder, analytic testing at this stage cannot adequately detect frauds, and the ingredient suppliers are often overseas and beyond the reach of effective enforcement actions.

Second, the CGMP rules put flexibility ahead of quality and safety concerns, allowing manufacturers to set their own label specifications and then choose their own tests for confirming label claims. As currently enforced, manufacturers may employ tests that cannot distinguish genuine products from chemically similar natural and synthetic compounds or which can be gamed in other ways. Manufacturers largely judge for themselves whether to test for known substitutes and contaminants. And while FDA acknowledged in connection with the CGMP rules that a combination of testing methods might be preferred to verify critical characteristics, like the identity of an ingredient, the rules expressly mandate the use of only one test.

Third, the CGMP rules do not require manufacturers to engage in any confirmatory testing to ensure that supplements are free of common allergens, even where products are marketed as containing no allergens (e.g. “Gluten-Free”).

Finally, the CGMP rules fail to define the key terms applied to dietary supplements or require manufacturers to disclose to consumers how those terms apply to a given product. These terms are poorly understood and manufacturers use them in ambiguous and conflicting ways. For example, with herbal supplements, the industry applies the term “extract” to a spectrum of products—from minimally processed plants to highly purified chemicals. When consumers buy a “natural” product—which typically features a root, a leaf, a flower, or a piece of bark on the label—they do not reasonably expect to receive a heavily processed chemical. Yet, more often than not, this is what they get.

State consumer protection laws demand more of manufacturers and retailers than the minimum requirements imposed by the CGMP rules, particularly as they relate to how those

³ Inspections of dietary supplement manufacturing facilities are exceedingly rare. In 2013—the most recent public numbers we have seen—the FDA inspected less than one in 25 registered dietary supplement manufacturing facilities. Given the rarity of an inspection, it is perhaps not surprising that well over half of those inspected were cited for alleged CGMP rule violations. Thus, increased resources for enforcement and more frequent inspections will be critical to the success of any reform.

products are marketed and sold to state residents. To resolve an investigation in New York, the largest specialty retailer of dietary supplements, GNC, agreed to a series of reforms designed to address the shortcomings of the federal regime as applied to its brand name herbal supplements nationwide. The agreement requires GNC to perform DNA barcoding to further authenticate the botanical ingredients used in GNC-brand herbal supplements, to conduct randomized allergen-testing on finished products, and to purchase botanical ingredients solely from suppliers who submit to third-party certification. The agreement also requires GNC to inform consumers of the highly processed, chemical nature of the company's extracted herbal products, both through in-store signage and on its website.

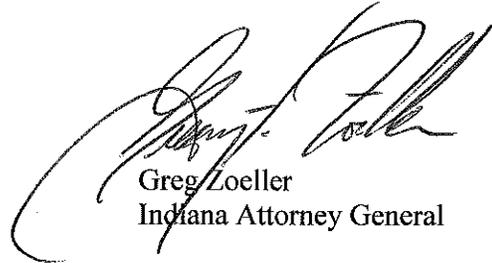
We tremendously appreciate the assistance of FDA in our ongoing efforts to rein in abuses in the dietary supplement industry. To address the fundamental problems affecting the national supplement market, however, federal leadership and oversight are needed urgently. Congress should act swiftly to expand FDA's powers to regulate the industry and substantially increase resources for enforcement. Until these reforms are put in place, however, we urge FDA to use every available tool at its disposal to strengthen dietary supplement regulations and their enforcement, including by initiating a comprehensive process to revise and strengthen the CGMP rules.

Please do not hesitate to contact us or our staff if we can assist you with any questions or concerns.

Sincerely,



Eric T. Schneiderman
New York Attorney General



Greg Zoeller
Indiana Attorney General