JEFF DUNCAN
3RD DISTRICT, SOUTH CAROLINA

COMMITTEE ON ENERGY AND COMMERCE
CHAIRMAN, SUBCOMMITTEE ON ENERGY, CLIMATE, AND GRID SECURITY
SUBCOMMITTEE ON INNOVATION, DATA, AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

DEPUTY REPUBLICAN WHIP

Congress of the United States
House of Representatives
Washington, DC 20515–4003

2229 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5301

303 WEST BELTLINE BOULEVARD
ANDERSON, SC 29625
(864) 224-7401

100 PLAZA CIRCLE, SUITE A1
CLINTON, SC 29325
(864) 681-1028

jeffduncan.house.gov

April 12th, 2024

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf,

It's come to my attention that a natural products manufacturer has reported dozens of branded supplements sold almost exclusively on e-commerce platforms that do not meet FDA requirements for potency claims on the label. Specifically, the claims on these products reflected abnormally high potency claims compared to the cost per bottle. They have communicated their findings to FDA, but I am told that FDA has seemingly taken no action in response.

Following the latest round of product policing, NOW Foods has found abysmal testing results tied to potency, labeling, contamination, adulteration, and heavy metal level issues across over 150 products tested to date since 2017.[1] To evaluate the quality and presence of particular ingredients, NOW analyzed samples using high-performance liquid chromatography with ultraviolet light detection. Additionally, an independent botanical testing laboratory verified the results from unopened bottles of each tested brand. According to the findings, each tested brand contained below 100% potency, with 18 brands containing less than 40% of label potency, and seven of the policing program's first-time testees registered 1% or less potency.

What troubles me most is that despite sharing each round of testing results with the FDA and the e-commerce platforms in question, I've been told that the natural products manufacturer claims they have never received a response or observed changes in the marketplace, with the same concerning brands continuing to be widely sold.

I believe FDA's failure to act on information from credible sources in this matter has consequences. As you may know, California, New York, and other states have proposed restricting access to certain dietary supplements as some state legislators understand them to be unregulated.

The new dietary ingredient notification (NDIN) requirement, widely considered to be inadequately used, is at the heart of FDA enforcement. More consistent enforcement would

[1] https://www.nowfoods.com/healthy-living/articles/nows-testing-results-berberine-products-december-2023

promote the agency's mission of protecting public health. I understand that only one company has submitted an NDIN for beta-alanine, yet substantial quantities of Chinese beta-alanine continue to enter the U.S. marketplace without an NDIN. FDA bears the burden of proving an ingredient is adulterated, and in the case of beta-alanine products coming from China, the FDA has no way of knowing whether the processes used to manufacture beta-alanine are safe.

Moreover, the FDA continues to advocate for new authorities, such as mandatory product listing, when a review of the agency's current tools has yet to be thoroughly examined. It was disappointing to learn that dietary supplements were excluded from the evaluation of the FDA's Human Foods Program conducted by the Reagan-Udall Foundation focused on the structure, leadership, authorities, resources, and culture provided recommendations that would equip the FDA to carry out its regulatory responsibilities, strengthen its relationships, and secure the nation's food supply.

Despite this exclusion, one finding seems particularly relevant for dietary supplements. The report found that *"FDA's Human Foods Program has at times appeared to be reluctant to take enforcement action unless they feel that, with certainty, the action could withstand legal challenges. This risk-averse culture also emerges in internal rules of governance intended to protect against possible negative outcomes... without the confidence to engage routinely, and transparently, with the external community, the FDA's Human Foods Program loses the opportunity to understand more fully the industry it regulates. External stakeholders observe that the Agency is often in 'listen-only' mode rather than having constructive dialogue that could yield better and more informed decisions."*

This risk-averse culture has handcuffed key dietary supplement issues, including the natural products manufacturer policing program previously referenced, NAC, and NMN. As you know, I've engaged the agency with letters requesting clarity on NAC and NMN. While I certainly appreciate the Agency's response, it left me and the industry with more questions than answers.

Compounding these issues is the decision to create a "super office" combining the Office of Dietary Supplement Programs with the Office of Food Additive Safety, which I believe will dilute the agency's focus on dietary supplements. When the dietary supplement program activities were elevated from a division to an office in 2015, the FDA stated, *"Elevating the program's position will raise the profile of dietary supplements within the agency and will enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources and capabilities to regulate this rapidly expanding industry."* Considering the ubiquity and proliferation of e-commerce platforms and online marketplaces since 2015, I would be interested to better understand the rationale for the agency's evolved thinking on the matter.

With this in mind, I hope you will consider providing information on the following topics:

1. According to NOW Foods, its policing program has exposed over 150 products tested to date since 2017. In that time, it my understanding that they've provided this information to the agency. When dietary supplement stakeholders provide information of this type to

the agency, how does the FDA evaluate the findings? Has the agency concurred with NOW and others' findings and taken action against fraudulent products?

2. In 2022, the FDA issued draft guidance stating that the agency will "for a limited time and in limited circumstances" exercise enforcement discretion while companies submit overdue NDINs. The FDA stated it is aware that some manufacturers and distributors have marketed products for which a premarket NDIN was required but never submitted. What was the basis for the FDA's change in policy on the requirement that manufacturers or distributors of an NDI that has not been present in the food supply as an article used for food or a dietary supplement that contains the NDI, must submit a premarket safety notification to FDA at least 75 days before introducing the product into interstate commerce? Why has the FDA not taken enforcement action against these violative products?

3. In 2022, you requested that the Reagan-Udall Foundation convene an Independent Expert Panel to conduct a comprehensive evaluation of the FDA Human Foods Program with the aim of strengthening FDA's food regulatory role. With the recent proposal to create a "super office" that incorporates the Office of Dietary Supplement Programs (ODSP) and the Office of Food Additive Safety, why was ODSP not included in the Foundation's evaluation of the Human Foods Program? Is there any consideration of a similar evaluation of ODSP in the future?

I look forward to receiving your response.

Sincerely,

Jeff Duncan
Member of Congress