U.S. FOOD & DRUG ADMINISTRATION

May 28, 2024

The Honorable Jeff Duncan
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Duncan:

Thank you for your April 12, 2024, letter to the Food and Drug Administration (FDA or the Agency) regarding the sale of supplements that reportedly do not meet requirements for potency claims on the label. Your letter also raised concerns about FDA's Human Foods Program (HFP) reorganization and how it will affect FDA's Office of Dietary Supplement Programs (ODSP), as well as FDA's new dietary ingredient notification (NDIN) program.

As we have discussed in previous letters, the new proposed HFP structure is designed to ensure the dietary supplements program remains a critical priority for the Agency. Under the proposed structure, the dietary supplement program will sit in the Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI). The vision for the new OFCSDSI is to modernize and strengthen the assessment of food chemicals and dietary supplements as well as facilitate safe and innovative ingredients for use in foods and dietary supplements. In this vision, ODSP will continue as an office and will serve to integrate the existing dietary supplement program within the broader foods program, while still retaining the distinct dietary supplement perspective to ensure the Agency is applying the appropriate statutory authorities to supplement-specific matters.

Our proposed structure does not diminish or otherwise decrease the importance of the dietary supplement program within FDA. ODSP will remain the lead office responsible for executing the Agency's dietary supplement responsibilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and resources or capabilities will not be reduced. In fact, FDA continues to prioritize additional resources and modernized authorities to strengthen our oversight of the dietary supplement marketplace.

We have restated your specific questions below in bold type, followed by our responses.

1. **According to NOW Foods, its policing program has exposed over 150 products tested to date since 2017. In that time, it's 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?**

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As a matter of policy, FDA does not take enforcement action based on third-party reports. If analytical testing is needed to support an enforcement action, FDA's practice is to obtain a regulatory sample and perform our own analytical testing to support product violations.

We are aware of the NOW Foods reports about their testing results; however, FDA asked the firm for more information about these results to evaluate the findings and determine how these reports might inform the Agency's future inspection or sampling plans. We recently received background information for some of the reports, and it is under review.

When a product is determined to be in violation of the FD&C Act, FDA considers many factors in deciding whether to initiate an enforcement action. Those factors include, among other things, Agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action. However, FDA does not discuss open investigations or plans for future investigations with third parties.

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?**

As you noted, FDA is aware that some manufacturers and distributors have marketed products for which a premarket NDI notification under section 413(a)(2) of the FD&C Act was required, but never submitted. The goal of the enforcement discretion policy discussed in the draft guidance is to encourage firms to correct past failures to submit an NDI notification, to increase the amount of safety information we have about NDI-containing dietary supplements in the marketplace, and to promote risk-based regulation. We note, however, that the guidance document remains in draft form, meaning the policy has yet to be implemented. FDA continues to evaluate comments submitted regarding this draft guidance as part of our consideration of a final guidance.

The enforcement discretion policy outlined in the draft guidance relates solely to the failure to file an NDI notification; it would not apply to for other reasons (e.g., a dietary supplement containing a dietary ingredients that present a significant or unreasonable risk of illness of injury) or to any other regulatory requirements that pertain to dietary supplements (e.g., labeling requirements). Further, the proposed enforcement discretion would only apply to past failures to submit the required NDI notification—i.e., the policy would be backward-looking only. We explained in the draft guidance that we do not

intend to exercise enforcement discretion for products introduced to the market after May 20, 2022 (the date the draft guidance was published in the Federal Register). Therefore, we have not changed our policy regarding the existing requirement for NDI notifications as described in sec 413(a)(2) of the FD&C Act.

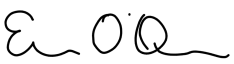
As previously noted, FDA considers many factors in deciding whether to initiate an enforcement action when a product is determined to be in violation of the FD&C Act.

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?**

   While the Reagan-Udall Foundation's (RUF) evaluation may not have included dietary supplements, ODSP is part of FDA's foods program and will benefit from the many changes that were identified in the RUF evaluation, including the proposal to reorganize into a unified Human Foods Program. The Agency did conduct a fairly comprehensive evaluation of the dietary supplement program as part of FDA's February 2019 announcement about new efforts to strengthen regulation of dietary supplements..

Thank you again for your interest in this issue. Please let us know if you have any further questions.

Sincerely,



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