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Lowell J. Schiller, J.D.
Principal Associate Commissioner for Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

COMMENTS ON RESPONSIBLE INNOVATION IN DIETARY SUPPLEMENTS BY THE
NATURAL PRODUCTS ASSOCIATION - Docket No. FDA-2019-N-1388

Dear Commissioner Schiller;

We previously presented comments at the public meeting in May of 2019 on this subject, we appreciate this opportunity to provide added commentary. By way of introduction, the Natural Products Association (NPA) is the leading and largest trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or finished products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents approximately 1,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements and health/beauty aids. Prior to my current role at NPA, I served as the Director of the U.S. Food and Drug Administration's Division (now Office) of Dietary Supplements, and one of a handful of FDA personnel whose signature appeared on New Dietary Ingredient (NDI) notification response letters.

Regarding the points to be addressed in the docket, we understand that the public meeting and added comment period are part of the agency's strategy to promulgate a final NDI guidance. While we understand that this is a priority to some at the agency, we believe that effort in this area should be secondary to a comprehensive NDI enforcement strategy, consistent with our comments at the public meeting. Does the agency have a plan and metrics that can provide the agency and the American people confidence that FDA is aware of the gaps in compliance as it pertains to NDIs? While much discussion has centered on asking congress

for new authorities, which is inconsistent with the present administration's goals, where there is
a

commitment to remove two regulations with every one that is added, nothing that has been presented from the agency's behalf has clearly demonstrated the metrics of compliance and where the actual gaps are regarding compliance. Additionally, considering the concern with resources, which are always limited at the agency, absent was any discussion on which tools enable the agency to be most effective while at the same time efficient and economical per current resources, assuming current authorities. This is a necessary step in effectively understanding what the gaps are and how they can be addressed.

Consistent with those points and with a clear understanding of agency operations, it is unclear as to why the agency doesn't currently have import bulletins (IB) or import alerts (IA) for NDIs that failed to file coming from non-domestic sources. Some FDA personnel said that this was a "*technical*" adulteration and thus may not rise to the necessary level of priority. However, this is inconsistent with prior and current agency action on "*technical*" adulteration. For example, IA 54-11 also references NDIs, the agency's reason for the alert is that "*FDA is not aware of any information demonstrating that androstenedione was lawfully marketed as a dietary ingredient in the United States before October 15, 1994. Nor is FDA aware of any information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, androstenedione is subject to the notification requirement for a new dietary ingredient in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. FDA has not received any such notifications.*"

Import alert 54-15 when it was issued, also references failing to file an NDI, it states "*Kratom is a botanical that qualifies as a dietary ingredient under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(ff)(1)]. When marketed as a dietary ingredient, FDA also considers kratom to be a new dietary ingredient under section 413(d) of the Act [21 U.S.C. 350b(d)] because, to the best of the agency's knowledge, there is no information demonstrating that this substance was marketed as a dietary ingredient in the United States before October 15, 1994. Furthermore, based on FDA's review of the publicly available information regarding kratom, there does not appear to be a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient. In fact, the scientific literature disclosed serious concerns regarding the toxicity of*



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kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms. In the absence of a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient, kratom and kratom-containing dietary supplements and bulk dietary ingredients are adulterated under section 402(f)(1)(B) of the Act [21 U.S.C. 342(f)(1)(B)], because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.” While other matters relevant to Kratom may influence agency action, at the time of the IA being posted, it was posted for a failure to file, which in the words of certain FDA personnel is a “*technical*” adulteration.

Another import alert, 54-14 has to do with a failure to meet good manufacturing practices (cGMPs), which is also considered by some to be a “technical” adulteration. Similarly, the foreign supplier verification program (FSVP), is based on keeping products out of the U.S. for failing to file. Therefore, a strategy to implement a general IB or IA for foreign NDINs that have failed to file is consistent with the agency’s current tenor on how to keep the food supply safe per FSVP, such action for NDIs must be step one for the agency. No amount of guidance or warning letters will send the message that a general IA/IB on non-compliant NDI imports will have. It’s not that safe products cant be sourced from foreign countries, however, if there is no enforcement against foreign NDI products that at a minimum have not presented their specifications to the FDA, why would a domestic firm ever see the NDI gate as a real priority to the agency. This is the fundamental challenge the agency is facing with respect to NDIs. Statutory requirements must be enforced uniformly, and to all in the space. One company can no longer ride on the coattails of another’s work. Guidance cannot be a greater priority than ensuring the proper interventions are deployed to make sure all in the supply chain have an equal footing and furthermore all Americans are protected.

Thank you for your consideration of this matter,

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President and CEO



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