

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

April 27, 2023

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

Dear Commissioner Califf,

I am writing to express my opinion that in accordance with the Code of Federal Regulations (CFR) Title 21 Part 15 Subpart B,¹ a public hearing should be scheduled to clarify the Food and Drug Administration's position on the use of Nicotinamide Mononucleotide (NMN) in dietary supplements.

It is my understanding that the FDA suddenly changed its position and advised companies of its determination that NMN is excluded from the definition of a dietary supplement, including a company that had previously received a so-called acknowledgment or "good day" letter from FDA in response to its new dietary ingredient notification (NDIN).

NMN has been used as an ingredient in dietary supplement products for years. The National Institutes of Health Dietary Supplement Label Database identifies the use of NMN in more than 600 dietary supplement products. Thus, the FDA's recent communications claiming that "NMN products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) of the [Federal Food, Drug, and Cosmetic Act] Act [21 U.S.C. § 321(ff)(3)(B)(i)]" is of great concern to many in the dietary supplements industry who seek to provide legal and safe products to consumers.

The sudden change of policy conflicts with historical precedent, including that the FDA permitted NMN to be included as an ingredient in dietary supplement products. Given the concerns raised over the Agency's recent and contradictory actions, I also respectfully request responses to the following questions:

1. As Congress looks across anti-competitive practices of e-commerce platforms, it has come to my attention that some platforms have restricted marketplaces for FDA-regulated products. Notably, in the dietary supplement space, platforms have chosen to restrict ingredients like NAC or NMN, which haven't been subject to final agency or regulatory action in the form of warning letters. Has the FDA contacted e-commerce platforms regarding the sale of NMN?

¹ 21 CFR 15.20 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=15.20>

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2. The FDA's Dietary Supplement website appears to present information on when NMN was first identified or designated as a drug. This raises the question of whether the drug exclusion criteria would preclude NMN from being included as an ingredient in a dietary supplement. Therefore, what is the Agency's position on the following issues:
 - a. How many structure-function claims notifications have been submitted to the FDA for review for NMN products under new dietary ingredient notifications (NDINs) requirements, and how many did the FDA determine inappropriate marketing?
 - b. What number of FDA enforcement actions were taken to address the marketing of NMN products by companies attempting to receive an NDIN for NMN-containing products?
 - c. What was the date when the FDA identified NMN being used in consumer products in the United States, both as a drug and as a dietary supplement or ingredient?
 - i. For NMN-containing products referenced by the FDA, please provide the analysis of the composition of the NMN present in the application for approval as a drug and the NMN dietary supplement composition.
 - d. What is the FDA's position on whether NMN would be banned from formulated dietary supplements under the drug exclusion criteria when the statute did not allow the FDA to remove products from the marketplace to the transparent advantage of a company marketing a drug with NMN as the active ingredient?
 - e. Does the FDA intend to remove the more than 600 NMN-containing products listed on the Dietary Supplement Label Database maintained by NIH from consumer access?

A public hearing would be incredibly beneficial as the dietary supplements industry seeks clarity on the FDA's actions regarding NMN. I look forward to receiving your response by May 11, 2023.

Blessings and Liberty,



Jeff Duncan
Member of Congress