U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

September 29, 2025

Steve Mister, President & CEO
Megan Olsen, Senior Vice President & General Counsel
Council for Responsible Nutrition
1828 L Street, N.W., Suite 810
Washington, DC 20036-5114

Sent via email to: molsen@crnusa.org

Re: Docket Number FDA-2023-P-1867

Dear Mr. Mister and Ms. Olsen:

This letter responds to your citizen petition dated May 9, 2023.[1] Your petition requests that the Food and Drug Administration (FDA or we) take certain actions with respect to the interpretation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and our associated regulatory decisions relating to Beta (β) Nicotinamide Mononucleotide (NMN). You ask FDA:

- To determine that the preclusion date referenced in the statute (*i.e.*, the date on which the "race to market" between a drug and a supplement is adjudicated) is the date the existence of substantial clinical trials are made public, not the non-public date on which an investigational new drug (IND) application goes into effect;
- To determine that "marketing" as used in section 201(ff)(3)(B) of the FD&C Act is not limited to marketing in the United States, nor does it require "legal" marketing of the ingredient;
- To determine that, for purposes of the race to market, evidence of marketing as a food or dietary supplement should be dispositive, unless FDA has met its statutory burden of demonstrating that the marketing was unlawful;
- To determine that "substantial clinical investigations" as used in section 201(ff)(3)(B) of the FD&C Act refers only to clinical trials that are adequately designed and powered to support approval of a drug, and does not refer to Phase I clinical trials; and
- To determine that FDA's prior affirmative statements recognizing the legal status of a particular article as a legal dietary ingredient prevents FDA from subsequently reversing that decision on the grounds of drug preclusion.

(Petition at 2). You also ask that FDA:

[1] See Citizen Petition from Council for Responsible Nutrition, submitted to the Division of Dockets Management, Food and Drug Administration, dated May 9, 2023 ("Petition").

> [I]mmediately issue guidance indicating how it will utilize the discretion conferred upon the Agency in section 201(ff)(3)(B) to create regulatory exceptions to drug preclusion that may arise under the statute through notice and comment rulemaking. Such guidance should provide clear criteria by which the Agency would determine that an article "would be lawful under this [Act]" and provide a framework for companies to petition for such rulemaking.

(Id.) We have carefully considered your petition and all comments submitted to the docket, including your own comment. In accordance with 21 CFR 10.30(e)(3), and for the reasons stated below and in our response to docket FDA-2023-P-0872, we are granting your petition in part and denying it in part.

DISCUSSION

I. We Incorporate by Reference Our Decision in Docket Number FDA-2023-P-0872, Which Addresses Many of Your Requests

Concurrent with the issuance of this response, FDA issued a response to a citizen petition from the Natural Products Association and the Alliance for Natural Health, (see Docket Number FDA-2023-P-0872 (FDA Response)). We incorporate by reference our response to that petition, which addresses many of the requests that you raise in your petition:

- We deny your request to determine that the preclusion date referenced in the statute (i.e., the date on which the "race to market" between a drug and a supplement is adjudicated) is the date the existence of substantial clinical trials are made public, not the non-public date on which an IND application goes into effect (see FDA Response at 7-9).
- We deny your request to determine that "marketing" as used in section 201(ff)(3)(B) of the FD&C Act is not limited to marketing in the United States (see FDA Response at 15-19).
- We grant your request to determine that "marketing" as used in section 201(ff)(3)(B) of the FD&C Act does not require "legal" marketing of the ingredient (see FDA Response at 19-22). Because we grant this request, we deny as moot your request to determine for purposes of the race to market that evidence of marketing as a food or dietary supplement should be dispositive unless FDA has met its statutory burden of demonstrating that the marketing was unlawful.
- We deny your request to determine that "substantial clinical investigations" as used in section 201(ff)(3)(B) of the FD&C Act refers only to clinical trials that are adequately designed and powered to support approval of a drug, and does not refer to Phase I clinical trials (see FDA Response at 11-15).
- We deny your request to determine that FDA's prior affirmative statements recognizing the legal status of a particular article as a legal dietary ingredient prevents FDA from subsequently reversing that decision on the grounds of drug preclusion (see FDA Response at 24-25).

We address your remaining request below.

II. FDA Will Not Issue Guidance Relating to Drug Exclusion Exceptions at This Time

Your petition requests that FDA issue guidance explaining how we will "utilize the discretion conferred upon the Agency in section 201(ff)(3)(B) [of the FD&C Act] to create regulatory exceptions to drug preclusion . . ." (Petition at 2). You recommend that the guidance "provide clear criteria by which the Agency would determine that an article 'would be lawful under this [Act]' and provide a framework for companies to petition for such rulemaking" (id.; see also Petition at 5).

FDA's guidance development process depends on various factors, including public health needs and the availability of FDA resources.[2] While we understand the desire for additional clarity, we must use our limited resources judiciously, focusing, for example, on priority matters, and so we decline to allocate resources to issue guidance on this topic at this time.

III. Conclusion

For the reasons stated above, in accordance with 21 CFR 10.30(e)(3), your petition is granted in part and denied in part.

Sincerely

Donald A. Prater -S

Digitally signed by Donald A. Prater -S
Date: 2025.09.29 09:38:25 -04'00'

Donald Prater, DVM
Principal Deputy Director for Human Foods
Human Foods Program

[2] See U.S. Food and Drug Administration, "Guidances," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidances#:~:text=There%20are%20several%20opportunities%20to,to%20comment%20on%20the%20Agenda; *see also* 21 CFR 10.115 ("Good guidance practices").