January 18, 2021

Weiyin Zhou
GM Assistant
Willy Nutra, Inc.
10 Monona Court
Derwood, Maryland 20855

Dear Weiyin Zhou:

This letter is to inform you that the notification that you submitted, pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), was received and filed by the Food and Drug Administration (FDA or we) on November 15, 2021. Your notification concerns the new dietary ingredient "β-Nicotinamide Mononucleotide (NMN)" that you intend to market as a bulk dietary ingredient.

According to your notification, the conditions of use are, "Take with water. 300 mg per person per day divided into 1 or 2 doses; at any time of the day." The target population is "Adults."

Under 21 U.S.C. § 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. § 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. § 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and we have significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing your new dietary ingredient, "β-Nicotinamide Mononucleotide (NMN)," will reasonably be expected to be safe under the conditions of use described in your notification.

FDA was unable to establish the safety of your new dietary ingredient, "β-Nicotinamide Mononucleotide (NMN)," based on the history of use information provided in your notification. For example, your notification provided vague history of use information and did not establish how the serving level of historically consumed NMN in the diet is quantitatively and qualitatively related to the proposed serving levels (e.g., the notification stated that the amount of

NMN consumed daily to be 5-10 mg, either from cooked food or raw food. This amount is 50-100 times lower compared to the proposed serving levels of 500 mg/day). In addition, your notification listed several products that contain NMN; however, you did not provide complete sales figures, commercial invoices, or amount of production. Without such information, it is unclear how NMN in the diet is qualitatively and quantitatively related to the proposed serving level of your new dietary ingredient.

FDA was unable to establish the safety of your new dietary ingreidnet, "β-Nicotinamide Mononucleotide (NMN)," based on the provided clinical study. For example, the subject of the study was very small (10 men), there was no placebo control, and the results of the study were based on a single daily dose instead of a dose response study. Because your clinical study was not a dose response study, FDA was unable to determine the no observed adverse effect level (NOAEL) for the study. Therefore, it is unclear how the history of use or other evidence of safety information will establish the basis of the safety of your dietary supplement containing the new dietary ingredient under the proposed conditions of use.

Your notification will be kept confidential for 90 days after the filing date of November 15, 2021. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1234. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and include an explanation of the basis for this belief.

If you have any questions concerning this matter please contact Steven Casper, Ph.D., Division of Research and Evaluation by email: NDITEAM@fda.hhs.gov.

Sincerely,

Ali A. Abdel-rahman -S

Digitally signed by Ali A. Abdel-rahman -S
Date: 2022.01.18 21:31:06 -05'00'

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