U.S. FOOD & DRUG ADMINISTRATION

May 24, 2022

(b) (4)

Dear (b) (4) :

This letter is to inform you that the notification that you submitted on behalf of Thorne Health Tech, Inc., 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 February 15, 2022. Additional information was received on March 22, 2022. The amendment was considered substantive and your filing date was reset to March 22, 2022. Your notification concerns the new dietary ingredient, "Nicotinamide Riboside Hydrogen Malate", that you intend to market as a bulk dietary ingredient.

According to your notification, the conditions of use are, "Daily intake of up to 1050 mg/day for up to 90 days." The target population is "Healthy adults (over 18 years of age and excluding pregnant and breastfeeding women)."

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.

After careful review, FDA has determined that the information in your notification and amendments does not provide a sufficient basis for us to conclude that "Nicotinamide Riboside Hydrogen Malate," the subject of your notification, is a "dietary ingredient" within the meaning of 21 U.S.C. § 321 (ff)(l) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. § 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total

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dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." The information in your notification and amendment was inadequate to demonstrate that your ingredient, "Nicotinamide Riboside Hydrogen Malate," is completely dissociated into its constituent ions, Nicotinamide Riboside (NR) ion and L-Malate, upon consumption under the acidic conditions of the gastrointestinal (GI) tract.

Because the information in your submission indicates that "Nicotinamide Riboside Hydrogen Malate" is not a dietary ingredient that can be used in a dietary supplement product, we are providing no response with respect to whether there is an adequate basis of safety for your product of commerce under 21 U.S.C. § 350b(a)(2) (section 413(a)(2) of the Act). However, please note that, under 21 CFR 190.6(f), failure by FDA to respond to a notification under section 413(a)(2) does not constitute a finding by the agency that a new dietary ingredient or the dietary supplement is safe or is not adulterated under 21 U.S.C. § 342 (section 402 of the Act). Therefore, insofar as it might be argued that your product is a dietary ingredient, it could be deemed to be adulterated under 21 U.S.C. § 342(f)(1)(B) (section 402(f)(1)(B) of the Act). In any event, you are not prohibited from submitting a new pre-market notification for "Nicotinamide Riboside Hydrogen Malate" under 21 U.S.C. § 350b(a)(2).

Your notification will be kept confidential for 90 days after the reset filing date of March 22, 2022. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1243. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and an explanation of the basis for this belief.

If you have any questions concerning this matter please contact Markeesa Scales, MPH, 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
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