DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

Mr. Daniel J. Hunter
COO, Green Rose LLC
1670 S. Robert Street #230
West St. Paul, Minnesota 55118

APR 2 0 2016

Dear Mr. Hunter:

This letter is to inform you that the Food and Drug Administration filed your notification, dated February 1, 2016, which you submitted to the Food and Drug Administration (FDA) 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)) on February 11, 2016. Your NDI notification concerned two ingredients, "gamma-aminobutryric acid (GABA) and L-theanine," which you intended to market in a dietary supplement product under the trade name of "Take5".

The conditions of use for your dietary supplement products were not provided in the notification.

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.

Title 21 of the Code of Federal Regulations (CFR) §190.6 was written to inform notifiers how to comply with the federal statute (21 U.S.C. 350b(a)(2)) establishing the requirements for a new dietary ingredient notification. Your notification concerning the above-mentioned new dietary ingredients do not comply with the requirements of 21 CFR 190.6 and is incomplete for five reasons as follows:

- Under 21 CFR 190.6(a) and 21 CFR 190.6(b)(4), you are required to provide the basis for your conclusion that your dietary supplement containing your new dietary ingredient will reasonably be expected to be safe [21 CFR 190.6(a)] and any reference to published information for which you based your conclusion should be provided in support of the notification [21 CFR 190.6(b)(4)]. You have not provided any opinion as to the safety of your dietary supplement product. References to support a conclusion that the dietary supplement containing your new dietary ingredient is safe are absent from your notification. Your entire notification consists of one page that is essentially a cover letter. Furthermore, you have not provided a safety narrative.

- Under 21 CFR 190.6(b)(3), you are required to provide a description of the dietary supplement that contains the new dietary ingredient. You do not provide this information in your notification.

- Under 21 CFR 190.6(b)(3) (i), you are required to provide the level of the new dietary ingredient in the dietary supplement. You did not provide this information in your notification.

- Under 21 CFR 190.6(b)(3) (ii), you are required to provide the conditions of use recommended in the labeling of dietary supplement product. No conditions of use are provided in your notification.

- Under 21 CFR 190.6(b)(4), you are required to provide history of use or other evidence of safety to comply with the statutory requirement for a reasonable expectation of safety. You did not provide this information in your notification.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Take5 containing gamma-aminobutyric acid (GABA) and L-theanine", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains 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. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of February 11, 2016. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management (see www.regulations.gov) as new dietary ingredient notification report number 912. 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 Dr. Fred Hines, Consumer Safety Officer, New Dietary Ingredients Review Team, at (240) 402-1756.

Sincerely,

Robert J. Durkin, Esq., M.S., R.Ph.
Acting Deputy Director
Office of Dietary Supplement Programs
Center for Food Safety
and Applied Nutrition