



Claire Kruger, PhD
Spherix Consulting, Inc.
11900 Parklawn Drive Suite 200
Rockville, Maryland 20852

NOV 03 2015

Dear Dr. Kruger:

This letter is to inform you that the Food and Drug Administration filed your notification, dated August 20, 2015, that 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 August 24, 2015. Additional information was received on October 13, 2015 and October 30, 2015. Your notification concerns a new dietary ingredient (NDI) identified as “Niagen.”

According to your amended notification, the recommended conditions of use of your ingredient are “Consumers are recommended to take no more than one capsule or one serving a day for up to 90 days. This provides a daily intake of Niagen of no more than 180 mg. Niagen capsules are not formulated for use in young children. Caution: If you experience any prolonged discomfort, flushing, itching, or tingling red rash on the skin discontinue use and consult your physician. As with any supplement, if you are pregnant, nursing, or taking medication, consult your doctor before use.”

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.

In accordance with 21 CFR 190.6 (c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not

precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

This letter supersedes FDA's response letter dated October 9, 2015.

Your notification will be kept confidential for 90 days after the filing date of August 24, 2015. 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 882. 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,

A handwritten signature in black ink, appearing to read "Robert Durkin". The signature is written in a cursive, flowing style.

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