



Virginie Wasiolek
Microphyt
713 Route de Mudaison
34670 Baillargues
France

SEP 19 2019

Dear Ms. Wasiolek:

This letter is to inform you that the Food and Drug Administration (FDA) filed your notification that you submitted to 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 July 9, 2019. Additional information was received on September 16, 2019. Your notification concerns your new dietary ingredient, which is a “Natural fucoxanthin extract (containing 2% Fucoxanthin) extracted from *Phaeodactylum tricornutum* microalgae” that you intend to market as a bulk ingredient called “PhaeoSOL.”

According to your amended notification, the recommended conditions of use are: “Fucoxanthin derived from *Phaeodactylum tricornutum* (referred to as PhaeoSOL) is proposed for use as an ingredient in dietary supplement products for the general adult population (not to be marketed to children, or pregnant or lactating women) at a maximum level of 5 mg fucoxanthin, equivalent to 218 mg PhaeoSOL, daily with no time limit; or a maximum level of 10 mg fucoxanthin, equivalent to 437 mg PhaeoSOL, for a maximum of 30 days.”

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 condition 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, you 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.

Your notification will be kept confidential for 90 days after the filing date of July 9, 2019. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1120. 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, Evaluation and Research Staff, at (240) 402-1756 or by email: Fred.Hines@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Durkin". The signature is fluid and cursive, with the first name "Robert" and last name "Durkin" clearly distinguishable.

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