DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 14 2016

Mr. John G. Moore
Venable LLP
575 Seventh Street, NW
Washington, DC 20004

Dear Mr. Moore:

This letter is to inform you that the Food and Drug Administration filed your notification that you submitted on behalf of C LAB Pharma International 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 1, 2016. Additional information was received on March, 24, 2016. Your notification concerns your new dietary ingredient (NDI) "copper niacin" that you intend to market as a bulk ingredient for addition to dietary supplement products.

According to your notification, the "level of the dietary ingredient will be such that the daily recommended serving is 100% of the reference daily intake (RDI) of copper, which for adults is 2.0 mg... Based on the molecular formula of the ingredient (including the chloride ion), this corresponds to 10.9 mg of copper niacin on a pure anhydrous basis. We note that this would also supply 7.7 mg niacin, which is 39% of the RDI for this nutrient.... Labeling will state that it is not intended for pregnant or lactating women. Labeling will suggest daily use with no limit on length of duration of 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.

Your notification will be kept confidential for 90 days after the filing date of February 1, 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 910. 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 Durkin

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