U.S. FOOD & DRUG ADMINISTRATION

Dannie Zhabilov
Cantech Pharma, Inc.
6108 Sumter Court
Frisco, Texas 75035

Dear Ms. Zhabilov:

This letter is to inform you that the Food and Drug Administration (FDA) filed your notification that you submitted 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 29, 2020. Your notification concerns a new dietary ingredient described as a combination of Enzolytics Pepsin from Porcine Liquid Supplement and Ascorbic Acid (Vitamin C) that you intend to market in a dietary supplement product under the trade name "Cantech Pharma ImmuneBooster."

According to your notification, the recommended conditions of use are: "[Take] 3mL/serving, 1 serving/day." The maximum daily serving of each ingredient in the dietary supplement is "12 mg pepsin and 150 mg ascorbic acid." Target populations: "All adults looking to boost their immune system."

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, 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 29, 2020. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1168. 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 CDR Jeanne Skanchy, R.Ph., Evaluation and Research Staff, at (240) 402-8790 and by email: NDITEAM@fda.hhs.gov.

Sincerely,

Ali A. Abdel-rahman -S

Digitally signed by Ali A. Abdel-rahman -S
Date: 2020.10.07 16:06:48 -04'00'

Ali Abdel-Rahman, Ph.D.
Director
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