DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

Mr. Harry Zhabilov
Enzolytics, Inc
6108 Sumter Court
Frisco, Texas 75035-7996

FEB 0 6 2020

Dear Mr. Zhabilov:

This letter is to inform you that the notification that you submitted on behalf of ZBGTECH Holding LLC[1], 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)), was received and filed by the Food and Drug Administration (FDA or we) on November 25, 2019. Additional information was received on February 2, 2020. Your notification concerns a new dietary ingredient that you describe as a combination of "Enzolytics Pepsin from Porcine (NDI 1083)" and "Hemp Oil." Your notification states you plan to market this ingredient in a dietary supplement called "ZBGTECH Holding compound liquid supplement[2]." As discussed below, any product containing the ingredient that is the subject of your notification would be outside of the definition of a dietary supplement in 21 U.S.C. § 321(ff) (section 201(ff) of the Act). As such, your "ZBGTECH Holding Compound Liquid Supplement" cannot be marketed as a dietary supplement.

You describe the NDI that is the subject of your notification as follows:

- "A combined suspension of Inactivated Pepsin Fragment (IPF) that comes from the purified extract of Pepsin from Porcine gastric mucosa powder under the NDI number of 1083 and hempseed oil."
- "The active ingredients are Irreversible Pepsin Fraction, which is an amino acid chain, and hempseed oil comprised of three essential fatty acids. The remaining components are residuals from the buffer solution and the final product is filtered through a sterile process and contains sodium chloride and ammonium sulfate as a preservative."
- "Hemp oil comes from the Cannabis Sativa L. plant that is most commonly used to produce hemp oil. The compound does not contain any psychoactive ingredients from the plant *Cannabis sativa*, only purified proteins and fatty acid molecules beneficial to immune support."

Based on information in your submission, the subject of your notification includes oil from hemp seeds.

This is the third notification you have submitted for this ingredient and product. In a letter dated August 29, 2019, FDA objected to your first notification for this ingredient and product,

1 We note that your notification was initially submitted on behalf of CANNAWORX, INC., and was changed to ZBGTECH Holding LLC by your amendment submitted on February 2, 2020.
2 In your amendment dated February 2, 2020, you informed FDA that the name of your dietary supplement has changed from Cannaworx Compound Liquid Supplement to ZBGTECH Holding Compound Liquid Supplement.

NDI # 1116, and informed you that your proposed product, "Cannaworx Compound Liquid Supplement," could not be marketed as a dietary supplement because of information which indicated that the hemp oil included in the subject of your notification contained 25.5% cannabidiol (CBD).

In a letter dated November 12, 2019, FDA objected to your second notification for this ingredient and product, NDI# 1128, and informed you that your proposed product, "Cannaworx Compound Liquid Supplement," could not be marketed as a dietary supplement because you did not adequately demonstrate the absence of CBD in your product, which previously was shown to contain CBD.

Your current submission does not support your claim that the hemp oil in your proposed dietary supplement, which was previously shown to contain 25.5% CBD and which you have stated is the same hemp oil from your prior two submissions, is now absent of any CBD. For example, you did not provide an analysis of your raw material (hemp oil) that identifies the components that are expected to be present. Furthermore, you use the terms "hemp seed oil" and "hemp oil" interchangeably throughout your notification even though these terms are conventionally understood to have different meanings. This is important because "hemp seed oil" is generally cold pressed, high in omega-3 and omega-6 fatty acids, and does not contain cannabinoids, such as CBD; however, "hemp oil" generally refers to oils from other parts of the hemp plant, including the flowering part, generally utilizes solvent extraction (including super critical CO_2 extraction), and, depending on the solvent, contains the full range of hemp constituents including cannabinoids. Your notification states that you obtain hemp oil from hemp seed by using super critical CO_2 extraction; however, you have not explained how using this extraction technique, which is different than the traditional methods used for producing hemp seed oil, with this raw material, will produce your purported NDI.

Based on the above information, you have not demonstrated that the subject of your notification does not include CBD. This ingredient renders your product outside the definition of a dietary supplement, and thus, your proposed product may not be marketed as a dietary supplement.

The definition of a dietary supplement is set forth in 21 U.S.C. § 321(ff) (section 201(ff) of the Act), which states in relevant part:

> (ff) The term 'dietary supplement' . . . (3) does . . . (B) not include – (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of Title 42, or (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Based on available evidence, FDA has concluded that CBD products are excluded from the dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B)(i) and (ii) (sections 201(ff)(3)(B)(i) and (ii) of the Act). FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

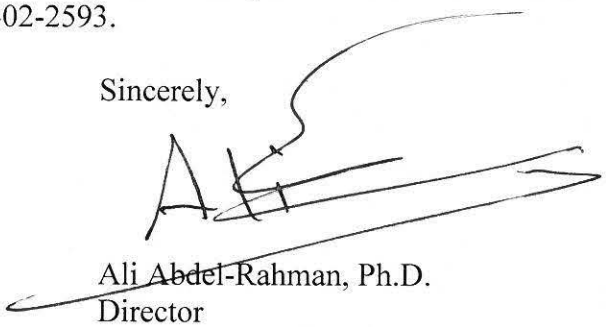
For more information regarding FDA regulation of cannabis and cannabis-derived products, please visit FDA's web site at: https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers.

Because the information in your submission indicates that your "ZBGTECH Holding compound liquid supplement" product is not a dietary supplement, we are providing no response with respect to whether there is an adequate basis of safety for your product under 21 U.S.C. § 350b(a)(2) (section 413(a)(2) of the Act), or whether any other regulatory issues exist in connection with your product. Please note that, under 21 C.F.R. 190.6(f), failure by FDA to respond to a notification under section 413(a)(2) does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. § 342 (section 402 of the Act).

Your notification will be kept confidential for 90 days after the filing date of November 25, 2019. 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 1135. 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. Steven Casper, Evaluation and Research Staff, at (240) 402-2593.

Sincerely,



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