

WARNING LETTER

Evol Nutrition Associates, Inc. d/b/a Red Dawn Energy

MARCS-CMS 576309 – APRIL 10, 2019

Product:

Dietary Supplements
Food & Beverages

Recipient:

Jeremy Nickels
Evol Nutrition Associates, Inc. d/b/a Red Dawn Energy
1775 West Oak Parkway Suite 850
Marietta, GA 30062
United States

Issuing Office:

Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, MD 20740-3835
United States

WARNING LETTER

VIA OVERNIGHT DELIVERY

RETURN RECEIPT REQUESTED

April 10, 2019

Evol Nutrition Associates, Inc.

d/b/a Red Dawn Energy

Attn: Jeremy Nickels

1775 West Oak Parkway

Suite 850

Marietta, GA 30062

Re: 576309

Dear Mr. Nickels:

This letter concerns your products Sleep Walker (sold in both liquid and capsule forms) and Red Dawn Liquid. These products are labeled and/or offered for sale as dietary supplements. Your Sleep Walker product labeling lists the substance Beta-phenyl-gamma-aminobutyric acid as a dietary ingredient, and your Red Dawn liquid product lists 4-amino-3-phenylbutanoic acid as a dietary ingredient. These ingredients are also called, among other names, phenibut, fenibut, phenigam, PhGaba, phenigamma, phenygam, β -(Aminomethyl)benzenepropanoic acid, and beta-(Aminomethyl)hydrocinnamic acid (hereinafter referred to as phenibut).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Phenibut is not a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Because phenibut does not fit in any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring phenibut in your product labeling as a dietary ingredient causes your products to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.[1]

The violation cited in this letter is not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violation identified above and for preventing its recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violation cited in this letter. Failure to promptly correct this violation may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violation. Include an explanation of each step being taken to prevent the recurrence of the violation, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Shawn Goldman, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov (mailto:Shawn.Goldman@fda.hhs.gov).

Sincerely,

/S/

William A. Correll

Director

Office of Compliance

Center for Food Safety and Applied Nutrition

[1] This warning letter does not address whether phenibut can be lawfully marketed in dietary supplements as non-dietary ingredients. For non-dietary ingredients intended for use in dietary supplements to be lawfully marketed in a dietary supplement, the substance must be used in accordance with a food additive regulation or be generally recognized as safe (GRAS) for its intended use (see section 201(s) of the Act (21 U.S.C. § 321(s)).

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